

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

4 HELSINN HEALTHCARE, S.A. and
ROCHE PALO ALTO, LLC,

CIVIL ACTION NUMBER:

Plaintiffs,

11-3962 (MLC)

-VS-

MARKMAN HEARING

8 | DR. REDDY'S LABORATORIES, LTD.,
et al.,

9 Defendants.

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
September 23, 2014

13 **B E F O R E:** THE HONORABLE MARY L. COOPER
UNITED STATES DISTRICT JUDGE

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24 Certified as True and Correct as required by Title 28, U.S.C.,
Section 753

25 /S/ Regina A. Berenato-Tell, RMR, CRR, CCR

1 **A P P E A R A N C E S:**

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25 ALSO PRESENT: JOSEPHINE LIU

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1 TRENTON, NEW JERSEY, TUESDAY, SEPTEMBER 23, 2014, 1:30 P.M.

2 (In open court.)

3 THE COURT: Good afternoon, everyone. Welcome.

4 Here we are in Helsinn versus Dr. Reddy, Sandoz, and
5 Teva with the lead action number 11-3962. And I'll take your
6 appearances in the order of the caption. Everyone else may be
7 seated.

8 MR. LIZZA: Good afternoon, your Honor. Charles M.
9 Lizza of the Saul Ewing firm, and with me is my partner
10 William C. Baton. And I'll have the Paul Hastings colleagues
11 identify themselves.

12 MR. DITTMANN: Good afternoon, your Honor. Eric
13 Dittmann from Paul Hastings on behalf of Helsinn.

14 MS. NI: Good afternoon, your Honor. Angela Ni from
15 Paul Hastings on behalf of Helsinn.

16 THE COURT: Fine. Thank you.

17 MR. WONG: Good afternoon, your Honor. Jovial Wong
18 from Winston and Strawn on behalf of the Teva defendants.

19 MS. TARANTINO: Good afternoon, your Honor. Mayra
20 Tarantino from Lite, DePalma, Greenberg, also on behalf of
21 Teva.

22 MR. SENDER: Good afternoon, your Honor. Stewart
23 Sender from Budd Larner on behalf of Dr. Reddy.

24 MR. IMBACUAN: Good afternoon. Michael Imbacuan from
25 Budd Larner on behalf of the DRL defendants.

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1 MR. D'AMORE: Good afternoon, your Honor. Matthew
2 D'Amore from Morrison and Foerster for Sandoz.

3 MR. ABRAHAM: Hello, Judge. Eric Abraham from Hill
4 Wallack, also on behalf of Sandoz. And I would like to
5 introduce to the Court Ms. Josephine Liu, who is in-house
6 patent counsel for Sandoz, also present in the courtroom.

7 THE COURT: Welcome. Welcome one and all. Good.

8 Okay. I have briefs. It looks as if defendants
9 consolidated your briefing for this claim construction
10 hearing; is that right?

11 MR. WONG: That's correct, Your Honor.

12 THE COURT: And the one issue that I have been told
13 we have to take up this afternoon is whether this preamble
14 language after the word "formulation" in Claim 1 of the '219
15 patent is limiting or not, right?

16 MR. DITTMANN: Correct.

17 THE COURT: Okay. It looks like, Mr. Dittmann,
18 you're poised to present.

19 MR. DITTMANN: Yes, I am, Your Honor.

20 THE COURT: Go right ahead.

21 MR. DITTMANN: May I approach, Your Honor? I have
22 copies of slides.

23 THE COURT: Oh, sure. Thanks.

24 MR. DITTMANN: Good afternoon, again, Your Honor. My
25 plan for this afternoon is to provide a very brief background

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1 discussion on some relevant items concerning this claim
2 construction dispute and then to jump right into the issue, as
3 you just mentioned, whether or not this disputed preamble
4 language limits the claims. And from a high level perspective
5 there's really two fundamental reasons why this language is
6 limiting, and one is that it provides antecedent basis for the
7 words "said formulation" in the body of the claims.

8 THE COURT: Now hold on. I don't mean to stop you so
9 fast, but the other side agrees that up to the word
10 "formulation" in the preamble everybody's fine with it to be
11 limiting, and, so, the disputed preamble language comes after
12 the word "formulation" in the preamble.

13 MR. DITTMANN: Yes, and I'm going to go through that
14 specifically to show you where there's agreement and where
15 there's disagreement, and I'll explain to you hopefully why we
16 think the language should be found limiting.

17 THE COURT: I'm following you.

18 MR. DITTMANN: Great. And the second independent
19 basis is that there was -- the intrinsic evidence makes clear,
20 including through clear reliance during prosecution, that this
21 language serves as a limitation of the claims.

22 So, very briefly, Your Honor may recall from our last
23 Markman hearing that this case -- these patents are directed
24 to what are known as setrons. They are used to treat emesis,
25 otherwise known as nausea and vomiting. And palonosetron is

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1 the specific setron that is used in the formulations of the
2 patents-in-suit.

3 Palonosetron is marketed in the United States as a
4 formulation for intravenous administration under the name
5 Aloxi®. And Aloxi® in the U.S. is specifically used to treat
6 chemotherapy-induced nausea and vomiting, which as we've
7 explained previously, can be a critical aspect of cancer
8 treatment in ensuring that patients can continue to take what
9 can be very hard medicines in the form of chemotherapy and
10 withstand them.

11 The patents-in-suit in this case -- there are four of
12 them -- we're focusing only on one today, the '219 patent in
13 red. All four of these patents are related. They stem from
14 the same priority application. They have nearly identical
15 specifications, and for purposes of today's discussion there's
16 no differences that are relevant. And all of them cover the
17 Aloxi® intravenous formulation.

18 THE COURT: All of them cover intravenous, all four
19 of these patents?

20 MR. DITTMANN: Yes.

21 THE COURT: Okay.

22 MR. DITTMANN: Now, I want to talk a little bit about
23 this disclosure of the '219 patent. Defendants have some
24 statements in their papers about the meaning of some of the
25 efficacy-relating statements in the '219 patent, and while the

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1 precise meaning of these statements are not necessary to
2 resolve today's claim construction dispute, they're helpful,
3 we think, to understand and provide support for why some of
4 the language is limiting.

5 So, to start with, the patents make clear that the
6 formulations serve two objectives. One, pharmaceutically
7 stable. We talked about that at length two years ago at the
8 last Markman hearing. That's not for today.

9 The second aspect that is relevant today is that they
10 can be used to treat emesis, including what I'll refer to as
11 CINV, chemotherapy-induced nausea and vomiting. As we can see
12 from the abstract, the present invention relates to shelf
13 stable liquid formulations of palonosetron for reducing
14 chemotherapy- and radiotherapy-induced emesis.

15 So, as we'll continue to go through the patent
16 disclosures I wanted to keep this in mind that there's really
17 two aspects to what's being discussed here, that these
18 formulations are both shelf stable and they're able to treat
19 this condition, CINV. And, in fact, one of the objects of the
20 invention is to provide a formulation of palonosetron with
21 increased pharmaceutical stability for preventing and/or
22 reducing emesis.

23 THE COURT: And the word "for" there modifies the
24 word "formulation." It is not modifying "stability."

25 MR. DITTMANN: Correct. That's what a formulation, a

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1 medicament is for; it is to treat a condition. It is not
2 to -- should not sit on a shelf and remain stable.

3 THE COURT: Right. Exactly.

4 MR. DITTMANN: So the summary of the invention -- in
5 fact, the very first aspect of the invention that's discussed
6 is a series of discoveries that support a surprisingly
7 effective treatment for prevention of emesis using
8 palonosetron. And it continues, "The inventors have
9 discovered that...only 1/10th of the amount of other
10 previously known compounds," other setrons that are mentioned
11 in the patent, but do not contain palonosetron, you can use
12 much lower amounts of palonosetron to treat emesis. And
13 that's one aspect of this invention.

14 And that's made clear...

15 THE COURT: Can I just stop you there for a second?

16 MR. DITTMANN: Sure.

17 THE COURT: In one aspect the inventor -- I'm just
18 reading from what is in the summary on the board. "The
19 inventors have discovered that formulations, which include the
20 active ingredient palonosetron require in some instances only
21 1/10th of the amount of other previously known compounds."
22 So, this invention doesn't say, Oh, we came up with the
23 surprising discovery that we can use one-tenth as much
24 palonosetron if we formulate it this way and we can still
25 succeed with this treatment, no.

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1 MR. DITTMANN: What they're saying is we're using
2 very low amounts, much smaller than the amounts used in other
3 setron products, you're correct, that known in the prior art.
4 And what they're saying is it is surprising that this molecule
5 palonosetron can be used at such low amounts relative to the
6 other setrons, and, again, it is important for treating
7 emesis, and we're talking about the amounts of palonosetron.
8 There's no discussion here of stability. That comes later.
9 That's another aspect of it.

10 It turns out, Your Honor, that low amounts of
11 palonosetron are both beneficial for stability, and they also
12 are able to treat emesis. And you'll hear about this more as
13 this case progresses, but that is really the fundamental
14 aspect is that it was surprising the stability that was seen,
15 but it was also surprising that there was efficacy at all,
16 given the prior art disclosures about palonosetron. We don't
17 need to get into the details of the prior art disclosures
18 regarding the amounts of palonosetron, but all I wanted to
19 illustrate was this invention is clearly talking about
20 efficacy aspects on the one hand and stability on the other.

21 Further on in the body of the specification, which was
22 cited in our briefs, there's some more disclosure, again,
23 focused on the efficacy aspects of this invention, and here,
24 again, we see the comments about the lower amounts of
25 palonosetron to treat emesis, and then it continues and talks

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1 about these lower dosages that can be used and administered
2 intravenously. And an example that's provided is 0.25
3 milligrams of palonosetron, and that example is exactly what
4 is specified in the claims-in-suit and, so, here, once again,
5 we're clearly disclosing in this patent that 0.25 milligrams
6 of palonosetron is effective or can be used to treat emesis,
7 including CINV.

8 Now, here what we have is the claim setting forth the
9 disputed preamble language, and what I have done here is the
10 highlighted language is what the parties are currently
11 disputing. There is no dispute, as I'll get to in a minute,
12 about this language, and the reason that I'm highlighting
13 these two terms, as I'm sure Your Honor is familiar with by
14 now, is that plaintiffs contend that one basis -- not the only
15 basis but one basis -- for saying that the disputed preamble
16 language is limiting is that this preamble language should be
17 taken as a whole. It is clearly describing and modifying the
18 word "formulation." Just because some words come before and
19 some come after, it doesn't change the fact that they're
20 describing the formulation.

21 THE COURT: That's what you're saying?

22 MR. DITTMANN: That's what we're saying.

23 THE COURT: Yes.

24 MR. DITTMANN: But I'm saying that's one basis.

25 There are other bases that I'll cover as to why this language

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1 is limiting. And, again, this is very briefly setting forth
2 the parties's positions that the highlighting language we just
3 saw plaintiffs say it is limiting; defendants say it is not.

4 THE COURT: Go back to that slide, would you?

5 MR. DITTMANN: Sure.

6 THE COURT: Okay. If the Court finds that the
7 disputed term is a limitation in whole or in part and should
8 be construed then they still don't need to be construed --

9 MR. DITTMANN: Right.

10 THE COURT: -- because they have their ordinary
11 meaning?

12 MR. DITTMANN: Everybody agrees they have their plain
13 meaning.

14 THE COURT: Okay.

15 MR. DITTMANN: Now, before we get into the merits of
16 whether this language is limiting or not, I did want to pause
17 and posit that we're still scratching our heads over why this
18 dispute is being raised by defendants. We're now in the
19 middle of expert reports. We have received the second round
20 from both parties submitted last week, and nothing -- and I
21 have reviewed the reports very carefully -- nothing I see sets
22 forth any argument that depends on defendants prevailing in
23 their position here. In fact, the only thing I can see is the
24 defendants are stating in their brief that they will assert a
25 written description defense if plaintiffs's position is

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1 adopted.

2 THE COURT: An enablement, I think, isn't that what
3 they said?

4 MR. DITTMANN: It is a written description argument.
5 There is a footnote at the bottom of the slide.

6 THE COURT: Lack of written description. Yes. Page
7 13, Footnote 12 of their reply brief.

8 MR. DITTMANN: In all honesty, Your Honor, we don't
9 expect to see this defense at trial, but, nevertheless, it has
10 been stated to be dependent on plaintiffs's construction being
11 adopted, not their own. But more than that, we don't -- we
12 have put in our briefs a number of times we don't see how this
13 dispute matters. The parties's experts don't seem to think
14 that matters. Defendants, nevertheless, raised this issue.
15 We believe that it is clear that this language is limiting,
16 and we're, frankly, concerned about the mischief of, well, all
17 of a sudden now there's a Markman ruling, and they're going to
18 make new arguments, even though we think they would be
19 untimely at this late stage, there's no reason for us to agree
20 that this language is not limiting when it is very clear that
21 it is. And I'll review that.

22 THE COURT: I don't think I ever heard of that kind
23 of scenario before. Every time I come out for a Markman
24 hearing it is because the parties have some notion of how
25 that's going to play into the strategy of the rest of the

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1 case. They don't tell me what it is usually. At least they
2 tacitly agree this matters, it matters or else they wouldn't
3 be putting us through this exercise of claim construction on
4 it.

5 Go ahead. It is your presentation.

6 MR. DITTMANN: So to begin with, defendants place a
7 lot of reliance in their briefs on legal principles, and
8 including this as an example of one that generally the
9 preamble does not limit the claims. And we see variance of
10 that throughout their brief.

11 But I want to start off with the notion to correct any
12 misunderstanding that that does not apply in this case.

13 Initially defendants took the position during the meet and
14 confer process that the entire preamble was not limiting, and
15 they said every part of it is not limiting. After the meet
16 and confer process was concluding on the day that we were
17 submitting joint claim construction charts they came in and
18 changed their position and said, Oh, wait, no, this language,
19 "pharmaceutical single-use unit-dose formulation" is limiting,
20 but the rest is not.

21 So, we have a situation where the preamble is limiting
22 by defendants's own admission, so this is not -- this is a
23 case where the preamble is limiting. So resort to general
24 principles is really not helpful to defendants. And we have
25 to look at the facts. And I'll also explain, if it becomes

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1 necessary that, in fact, the "single-use unit-dose" language
2 that defendants claim to be the structural aspects of this
3 preamble, in fact, is not. You can just see by the word
4 "single-use" it is referring to how you use these
5 formulations. "Single-use" refers to the fact that it is
6 administered once to a patient and discarded.

7 And, so, putting that aside, though, the fundamental
8 point that I want to make is these sort of general principles
9 about preambles generally not limiting do not apply in this
10 case because we have already all agreed that this preamble
11 does at least limit in part.

12 So, then getting to the specifics, again, as I
13 mentioned earlier, plaintiff's position is the preamble is one
14 limitation. And it describes the formulation. And we don't
15 think it is proper to break it up into parts, but that is what
16 defendants have done. They have sort of carved out the front
17 part of the preamble and said it is limiting, so that is not
18 in the case any longer. And they have made arguments about
19 two other parts of that preamble phrase, so I'm going to deal
20 with them...

21 THE COURT: But you don't have any authority for the
22 notion that a long run-on clause consisting of several phrases
23 has to be interpreted as a single limitation.

24 MR. DITTMANN: I agree it doesn't have to be, Your
25 Honor. Certainly, if there is a long list of phrases that

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1 don't relate to the formulation, but here everything, as I'll
2 explain, relates back to the formulation and describes the
3 formulation.

4 And, certainly, with respect to this first phrase "for
5 intravenous administration to a human," frankly, we don't see
6 much of a dispute here. I'll go through the reasons for that.
7 And the first one is that defendants's responsive brief, they
8 concede that intravenous preamble language from the original
9 patents-in-suit, the '724, '725, and '424 patent they admit
10 that those are limiting. And as I'll explain to you that
11 phrase "intravenous" in the preamble of the other patents has
12 the same meaning as "for intravenous administration." There's
13 no distinction between those two phrases. And, in fact, the
14 defendants's experts have provided testimony admitting this.

15 The second point is that "for intravenous
16 administration" provides structural antecedent basis for "said
17 formulation" in the body of the claims. And I'll explain
18 that, but it is sort of common sense; when you're putting
19 something directly into your blood, there are special
20 requirements to make sure that patients aren't harmed, there
21 aren't irritations, there are special considerations for
22 intravenous administration formulations, and, therefore, that
23 has an effect.

24 THE COURT: Also, I notice that the specification,
25 which I don't know how common it is to how many other patents,

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1 mentions both "intravenous" and "oral," but when we get to the
2 claims we only have two independent claims here in this
3 patent, and they're both clearly for intravenous.

4 MR. DITTMANN: Yes. And, your Honor may recall in
5 our opening brief you went through a very long summary of the
6 prosecution where some oral prior art formulations were
7 distinguished because the claims of these patents are focusing
8 on the I.V. aspect. This is about I.V.

9 And the last independent basis is there is some
10 relevant prosecution history that I'll discuss that makes
11 clear that intravenous is a limitation of these claims.

12 So, again, the first point here is that, again, we had
13 a summary of prosecution histories from four separate
14 applications, all of them the family that led to this patent,
15 the '219 patent, and over and over again the patentees
16 distinguished oral prior art solutions as not being
17 intravenous.

18 And now defendants don't contest this clear reliance.
19 They say we agree. "Intravenous solution," "intravenous
20 isotonic solution" and the like from these various patents are
21 all limitations, and those are preamble -- those are in the
22 preamble. And they say it is because it affirmatively recites
23 essential structure, and we agree, "intravenous" does convey
24 essential structure, as I just mentioned.

25 But the issue here is that when you look at what

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1 defendants, for example, Claim 1 of the '724 patent, what they
2 concede to be limiting is indistinguishable from what we have
3 in our claim of the '219 patent. That is because
4 "intravenous" is Latin for inside the vein. It is talking
5 about what you do with a formulation. You're putting the
6 formulation inside the vein of a human. And it is a
7 prepositional -- the prepositional phrase "for intravenous
8 administration" is the same thing as the use of "intravenous"
9 as an adjective. There's no difference.

10 And, frankly, defendants's experts wouldn't get up here
11 and tell you anything differently, and we know that because we
12 have their testimony, and I can walk you through that. For
13 example, Dr. DeLuca, one of defendants's experts in one of his
14 expert reports states that "intravenous solution is a
15 parenteral liquid solution dosage form that is administered
16 through injection into a vein of the human body." That is
17 essentially saying what I'm saying, that they're the same. An
18 intravenous solution is administering the solution through a
19 vein intravenously.

20 THE COURT: Nobody really disputes that we're talking
21 about medicine for a human being, right?

22 MR. DITTMANN: We certainly don't, Your Honor.

23 THE COURT: I mean, you can have an intravenous
24 veterinary solution, I'm sure?

25 MR. DITTMANN: That may be, but we think it is very

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1 clear, again, from the claims that we're talking about
2 administering to a human, and that's the subject that needs
3 chemotherapy-induced nausea and vomiting treatment. I'm not
4 aware of any animals that undergo chemotherapy.

5 THE COURT: Yes, they do.

6 MR. DITTMANN: Do they?

7 THE COURT: They absolutely do.

8 MR. DITTMANN: I'm not aware of at least antiemetics
9 and these sort of palonosetron solutions being used, but,
10 nevertheless, points well taken.

11 Now, we have Dr. DeLuca separately stating and
12 summarizing one of the prior art articles, the Tang reference,
13 he says, "The Tang discloses the use of an intravenous
14 solution of palonosetron to treat PONV." "In particular, Tang
15 disclosed that each dose of medication used was an isotonic
16 sodium chloride solution of palonosetron administered
17 intravenously." This is not debatable. These are the same --
18 this means the same thing, these two sets of words.

19 Dr. Frame made a similar admission. I won't belabor
20 the point with respect to another prior art reference, and Dr.
21 Kirsch, another one of defendants's experts, he equates
22 "administered through intravenous administration" to "an
23 intravenous formulation."

24 What we have is over and over again, and if anything
25 more was necessary, even last month defendants's expert Dr.

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1 DeLuca sets forth Claim 1 of the '219 patent, and he
2 summarizes his opinions that saying, "it would have been
3 obvious to develop an intravenous solution with common
4 components in the prior art." Again, "intravenous solution"
5 is no different than "for intravenous administration."

6 So, that's we think -- number one, we think
7 defendants's admission puts this issue to bed. But even if
8 there was some argument to say that these words had any slight
9 difference in meaning defendants say that, Well, you can't use
10 the prosecution for a word like "intravenous" and then apply
11 it to a different term like "for intravenous administration."
12 They have to be the same claim language is what defendants
13 say, but that's not the law. The Federal Circuit has made
14 clear that the proper inquiry in such a circumstance is
15 whether the scope of the claim limitation is substantially the
16 same in the subsequent application as it is, for example, in
17 the parent application.

18 And the Masco case we cited in our opening brief
19 provides one example; in this case the parent application had
20 the term "positively driving" as part of a means plus
21 function, and statements regarding that claim term was used to
22 construe the phrase "to drive." Just one example. They don't
23 have to be exactly the same language. They have to be either
24 the same or substantially the same.

25 Now, bringing us back to our point about antecedent

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1 basis, defendants provide a test where they say, Well, the
2 antecedent basis in this case is if it's the structural part
3 of the preamble they say that's what comes in through this
4 antecedent basis. But, again, there really can't be a
5 legitimate dispute that when a person of skill in the art sees
6 "for intravenous administration to a human" that conveys
7 certain structural requirements for the formulation. Not only
8 that it be isotonic and sterile like the claims already
9 require, but that it be free of pyrogens, these substances
10 that can raise body temperature and cause fever. It also has
11 to be free of particulate matter. This is very different than
12 if you're taking something and ingesting it orally and you
13 have the benefit of your low pH of your intestinal system in
14 your stomach to handle these formulations. So we think even
15 if that's the test, that's readily met here.

16 Now one last point, your Honor, and this one is
17 important to keep in mind, as well; the word "isotonic"
18 everyone agrees is a limitation of these claims. No one
19 disputes that "isotonic" is not limiting. And I'm going to
20 show you that in the parent application for this patent that
21 "isotonic," that claim term was described to mean to refer to
22 intravenous formulations, and I'll show you that now. In an
23 appeal brief in the parent application in distinguishing, once
24 again, oral formulations --

25 THE COURT: This is appealing to the Patent Office

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1 Board of Appeals or something?

2 MR. DITTMANN: Correct.

3 THE COURT: Go ahead.

4 MR. DITTMANN: So in that appeal brief -- and we'll
5 come back to this brief later for a different reason -- but in
6 that brief we're distinguishing oral formulations, and in
7 making that argument the applicants say that, "this ignores
8 the requirements of the claims for isotonicity," which is,
9 again, a claim requirement to the '219 patent, "which is a
10 requirement only for intravenous formulations."

11 So, the point is this: We think it is crystal clear
12 that the preamble phrase "for intravenous administration" is
13 limiting, but even if we're wrong it still is a requirement
14 through the word "isotonicity" in the body of the claim, so
15 even if the defendants prevailed on the preamble point it is
16 still a limitation of the claims either way.

17 THE COURT: You mean to be intravenous is necessarily
18 implied by this word "isotonic."

19 MR. DITTMANN: And that's exactly what the applicants
20 are saying in this prosecution document. They tell the Patent
21 Office our claims require isotonicity; that distinguishes us
22 from oral because isotonicity is a requirement for intravenous
23 formulations. If this were a case, your Honor, where we were
24 alleging the defendants's oral formulations somehow were
25 infringing this would be the sort of thing where it would

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1 become frivolous for us to say that "intravenous" is not a
2 requirement of the claims. I submit for at least that reason
3 it has to be a limitation here.

4 "To reduce the likelihood of CINV," that's the last
5 part of this preamble phrase. And there are two basic points
6 here, as well. Like what we just saw with "intravenous" this
7 phrase was clearly relied upon during prosecution, including
8 to distinguish the prior art. And the phrase is also a
9 fundamental characteristic of "said formulation" in the body
10 of the claims.

11 Now, very quickly, again, going back to the point about
12 you can't rely on broad general principles, the defendants's
13 statement about generally limiting -- not limiting when it's
14 in the preamble, there's an exception that unless there's
15 reliance in the prosecution. We have cited the Catalina point
16 just as defendants did for this, and it makes clear that clear
17 reliance during prosecution can render preamble language
18 limiting. And in this case they mentioned the example of
19 distinguishing prior art, but as I'll get to in a moment, you
20 can also distinguish -- or you can also rely on preamble
21 language to get over a 112 rejection, as well, and that causes
22 the language to be limiting.

23 THE COURT: I get tired of remembering those
24 subsections.

25 MR. DITTMANN: 112 is the disclosure requirements

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1 that the claims have to provide a written description of the
2 invention and enabling disclosure, amongst some other
3 requirements, but for purposes of today we can talk about
4 enablement since that is what happened in the parent
5 applications.

6 So, I'll try and go through this relatively quickly
7 because we have set this forth in our papers, your Honor, but
8 to boil it down --

9 THE COURT: I think the new version of 112 actually
10 gives us subparagraphs.

11 MR. DITTMANN: Which is nicer. A little bit more
12 convenient.

13 The parent application, the '724 patent, again, this is
14 the original parent application that ultimately led to the
15 '219 patent, this claims that were originally filed were
16 rejected because they had this language "preventing emesis."
17 The examiner didn't like that and said, you know, while you're
18 enabling for reducing, I don't like "preventing."

19 First of all, there's no point in the examiner
20 rejecting those claims, unless they mean something and they
21 limit them, but putting that aside, what the applicants did is
22 they removed that language that the examiner didn't like and
23 they put in a virtually identical preamble language to what
24 we're talking about today, "reducing the likelihood of
25 emesis."

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1 THE COURT: And they put it in the preamble?

2 MR. DITTMANN: They put it in the preamble. Right.

3 THE COURT: So, the examiner was quibbling about the
4 preamble?

5 MR. DITTMANN: The examiner is making clear that the
6 examiner considered the preamble to limit, otherwise there
7 would be no reason to reject those claims. If it is not a
8 limiting preamble it doesn't matter for purposes of 112. But
9 even as importantly, the applicants come and put this language
10 in the claims, which, again, is nearly identical to the
11 language we're talking about in the '219 patent, and they say
12 the claims are directed towards reducing emesis or reducing
13 the likelihood of emesis. And, so, this claim amendment and
14 argument to overcome a 112 rejection, we submit, is one reason
15 to find the nearly identical language "to reduce the
16 likelihood of CINV" to be limiting under the Fantasy Sports
17 case that we cited.

18 This same exact amendment and arguments were made in
19 two other related applications. Exact same language was made,
20 you know, was submitted. The amendments were made. The
21 arguments were made multiple times, and the examiner relented,
22 and the 112 argument was overcome for those reasons.

23 Now, the defendants they really don't quibble with the
24 principle that if you overcome 112 using the preamble language
25 an argument that it can be limiting; they say, oh, we miscite

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1 the Fantasy Sports case because in Fantasy Sports only the
2 word "computer" was found limiting. The rest of it "for
3 playing football based upon actual football games" was not.

4 Well, first we'll put aside that they seem to be trying
5 to make an argument that only structural limitations can be
6 limiting when you overcome a 112 rejection, but let's put that
7 aside and imagine that defendants are correct about that
8 point, which we don't agree with. Fantasy Sports made it
9 crystal clear that the entire phrase "a computer for playing
10 football based upon actual football games," that phrase
11 constitutes a limitation. Defendants cite to different parts
12 of the opinion referring to the, quote, "computer limitation."
13 It is clear that's shorthand for the entire preamble phrase
14 that the Court -- Federal Circuit expressly found limiting.
15 But, again, that's just point number one.

16 The more important point is that even if you applied
17 defendant's test that, well, they said only the "computer"
18 language was amended. That's the only part they say was
19 amended, and that's important for purposes of what's limiting.
20 If you apply that test to our claims, again, what was amended
21 is "reducing the likelihood of emesis," exactly what we're
22 talking about except for, of course, emesis in our case is a
23 specific type of CINV. So, defendants make the argument that,
24 well, when you get a 112 rejection over preamble language you
25 can just delete the preamble language, and you can obviate it

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1 that way, and that may be true, but the fact that the
2 applicants didn't do that and they amended the language to
3 overcome the rejection shows, proves that it is a limitation.

4 Defendants make a separate argument relating to these
5 parent applications, and, by the way, I just want to pause for
6 a moment on this that defendants when it comes to intravenous
7 preamble language they say it has to be the exact term in
8 order for the parent prosecution to matter. But when we get
9 to the "reducing the likelihood of emesis" language they have
10 no trouble with equating "reducing the likelihood of emesis"
11 with "reducing the likelihood of CINV." I think that's
12 inconsistent. But putting that aside, they rely on this
13 appeal brief, and their argument is that, well, that because
14 "reducing the likelihood of emesis" doesn't appear --

15 THE COURT: You lost me. Actually, you're talking a
16 little bit fast for purposes of an on the record session.

17 MR. DITTMANN: My apologies. I'll slow down.

18 THE COURT: We have the world's best court reporter
19 here taking down every single word perfectly, but sometimes I
20 get a little lost.

21 MR. DITTMANN: Please feel free to slow me down any
22 time.

23 THE COURT: Okay.

24 MR. DITTMANN: So I want to just first make the point
25 that remember earlier defendants's argument about intravenous.

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1 They say the word "intravenous" is different than "for
2 intravenous administration," and because of that difference
3 they say you can't rely on prosecution statements relating to
4 "intravenous" to apply to a different claim language "for
5 intravenous administration." They make that argument. I have
6 explained why that argument is not correct under the law. But
7 I simply want to point out that when it comes to the separate
8 preamble language "reducing the likelihood of emesis" they're
9 attempting to use prosecution statements relating to that
10 claim language, that preamble language that is different from
11 the preamble language in the '219, they're using it
12 affirmatively now to say, well, this proves that this is not a
13 limitation. So there is inconsistency in their positions.
14 Either the parent prosecution is relevant if it is similar
15 claim language or it is not.

16 But, more importantly, defendants's reliance on this
17 appeal brief lists -- and I want to explain what their
18 argument is just to make sure we're all clear on this. They
19 say that because the applicants did not include in this list
20 here, did not include "reducing the likelihood of emesis" as
21 one of the claim formulation features that that proves that
22 "reducing the likelihood of emesis" is not a limitation.

23 THE COURT: Of the '219?

24 MR. DITTMANN: Of the '219, even though this is a
25 statement from a previous application, but, again, putting

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1 that aside, the M.P.E.P. is very clear that this summary of
2 claimed subject matter that has to be provided, it only
3 relates to subject matter of the claims involved in the
4 appeal. It doesn't say every single claimed subject matter
5 has to be summarized. It is what's involved in the appeal,
6 and this part was not quoted in defendant's briefs, and we
7 wanted to make sure this was clear that it has to be involved
8 in appeal, and we just went through that the "reducing"
9 preamble language, "reducing the likelihood of emesis" that
10 was no longer at issue because they had overcome the
11 examiner's rejection. There's no need to talk about that
12 limitation when it wasn't relevant to an objection that was
13 being discussed in this particular appeal.

14 And, frankly, defendants's Markman arguments from
15 earlier in this case we think was correct. They said, "The
16 claims of the asserted patents," these original '724, '725,
17 and '424 patents "are directed to pharmaceutically stable
18 intravenous palonosetron formulations that can be used for
19 reducing or reducing the likelihood of emesis." We think
20 that's correct.

21 Now, there's an independent basis for finding this
22 language in the '219 patent limiting, which I think is very
23 clear. This is from the '219 prosecution itself, the
24 application that issued as a '219 patent. It is in examiner
25 interview summary, so it is the examiner writing what was

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1 discussed with the applicants, and it identifies --

2 THE COURT: Is this the last thing that happens in
3 this prosecution history before the patent is approved or is
4 there more?

5 MR. DITTMANN: I believe this was -- yes, it was.

6 THE COURT: Frequently the interview is the last
7 exchange between the parties before the issuance notice is
8 sent. Would that be the case here?

9 MR. DITTMANN: It can be.

10 THE COURT: No, here.

11 MR. DITTMANN: In this case, yes, this was at the end
12 of the prosecution. But, also --

13 THE COURT: See, I have been given only portions of
14 the file history, and that always leaves me a little bit --

15 MR. DITTMANN: Right. How much is this in the volume
16 of paper?

17 THE COURT: That always leaves me just a little bit
18 unsure of at what stage what was being discussed. But go
19 ahead. I rely on these parties, you and your adversaries, to
20 give me the pertinent portions of any of these histories, and
21 I don't ask you to give me the whole file wrapper.

22 MR. DITTMANN: Some of them can be so huge. I don't
23 think you would want them.

24 THE COURT: I know.

25 MR. DITTMANN: But, again, this prior art being

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1 discussed, this is -- it includes Tang, and, by the way, the
2 '219 prosecution was relatively small because there was a lot
3 of prosecution activity in the original patents. So, you
4 know, this again is a more different way of claiming this
5 Alox® formulation, so --

6 THE COURT: Could I just stop you there and ask: It
7 never is clear to me how so many patents get issued for,
8 basically, you know, very, very similar facets of
9 pharmaceutical formulations or uses. And here in this case
10 we're going to be at trial, we're probably still going to be
11 hearing about four patents, the ones that we have listed and
12 you tell me they're all for intravenous forms of the same
13 drug, Alox®, palonosetron. So, you know, in what way these
14 patents differ and are similar I don't know.

15 MR. DITTMANN: This patent-at-issue today has a
16 specific recitation of a very particular dose 0.25 milligrams
17 in a 5 milliliter solution, whereas some of the previous
18 claims referred to a concentration of palonosetron of 0.05
19 milligrams per milliliter, and we think that conveys a fairly
20 limited amount of dosages and volumes, but this patent that
21 we're talking about today is very specific 0.25 exactly, 5
22 milliliter solution.

23 THE COURT: Okay. Thank you.

24 MR. DITTMANN: During this examiner interview the
25 examiner summarizes what was discussed, and, again, it is

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1 prior art being discussed, Tang, and she says that
2 Mr. Sullivan, who was the prosecuting attorney for plaintiffs
3 in response to these prior art assertions being made he
4 highlighted the limitations that were in the claims,
5 including, so these are not all of them, but he is including
6 "limitations of the claims relevant to this prior art," and
7 one of them is "cancer chemotherapy-induced nausea and
8 vomiting" amongst others. The examiner goes on and talks
9 about Tang, describing a dose-ranging trial in PONV. PONV, as
10 your Honor may recall, is post-operative nausea and vomiting,
11 a related, but different form of emesis than CINV.

12 THE COURT: And it gets a higher dosage, I think,
13 generally?

14 MR. DITTMANN: Generally the CINV gets the higher
15 dosage than the PONV. The PONV is less. Yes.

16 THE COURT: I misread that.

17 MR. DITTMANN: And, so, here we have a situation in
18 the prosecution of the patent-at-issue defendant said there's
19 no evidence that we relied upon the CINV language. Well, here
20 we are. The examiner stating this a summary of what was
21 argued by the applicants relying upon chemotherapy-induced
22 nausea and vomiting language to distinguish the prior art.

23 THE COURT: Okay. So, Tang had to do with this other
24 use, which is post-op, post-operative, whereas this
25 application that resulted in the '219 is for cancer

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1 chemotherapy-induced emesis, right?

2 MR. DITTMANN: These PONV and CINV conditions are
3 related, but, again, they're different. They're different,
4 but they are related, and, again, I think your Honor was
5 accurate that there's a dosage relation that one takes more
6 dose than the other. But what we can't deny is that the
7 applicants state very clearly when they identify the
8 limitations in the claim the examiner expressly writes this
9 language, which was based on arguments from Mr. Sullivan.

10 THE COURT: So, in other words he is trying to
11 distinguish prior art in the form of this Tang patent that
12 addresses PONV, whereas the current application is addressing
13 CINV?

14 MR. DITTMANN: CINV. And, if I can give you a little
15 context of what's happening here is this Tang reference
16 discloses that you need at least 2 milligrams to have partial
17 efficacy in PONV, and what we are arguing to the Patent Office
18 is, well, look, if you need at least 2 milligrams for PONV and
19 only get partial efficacy, there's no way 0.25 milligrams for
20 CINV, which typically requires more dose could be obvious. So
21 we're using Tang to suggest that 0.25 milligrams for CINV
22 couldn't possibly be obvious based on the disclosure of Tang.

23 THE COURT: So, it is not just the wooden distinction
24 between a patent directed at a PONV therapy and another patent
25 directed at CINV. It is more than that. It is that the

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1 dosage --

2 MR. DITTMANN: Yes.

3 THE COURT: -- comparison produced some surprises.

4 MR. DITTMANN: Yes. The Tang study we think was --
5 suppose it would have found the results of Helsinn's clinical
6 study showing a very low-dose of palonosetron being effective
7 for CINV to be very surprising in terms of what Tang taught in
8 the prior art. Tang suggested you need a much higher dose.

9 THE COURT: Well, we will get there, but your
10 adversaries say, so, good; why aren't the clinical -- or at
11 least the lab results of this therapeutic effect then
12 contained in the specification for the '219 patent? But I'm
13 sure you'll get there.

14 MR. DITTMANN: Yes. To be clear, your Honor, that is
15 the written description defense. It is not a claim
16 construction dispute. But just to quickly preview that
17 defendants have a fundamental misunderstanding of the law with
18 respect to the written description defense that we'll make
19 very clear to your Honor at the appropriate time, but I can
20 tell you that no matter how you view the specification there
21 cannot be any doubt that it provides written description
22 support for what's claimed, the formulation that's claimed as
23 being capable of treating CINV a person of skill in the art
24 reading that specification wouldn't have any doubt. That is
25 the case based on that disclosure, but we'll address that at

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1 the appropriate time if it ever comes.

2 And, so, basically, I want to make sure that we're
3 clear on --

4 THE COURT: Incidentally, while we're switching
5 slides, we will take like a five-minute recess before your
6 adversaries have to get up and speak just so everybody is not
7 starting to get uneasy in the room.

8 MR. DITTMANN: It was going to slow me down, your
9 Honor.

10 THE COURT: And you have all the time you need, both
11 sides.

12 MR. DITTMANN: Thank you. The Vizio case we cited we
13 think is instructive. It is an analogous situation where it
14 is an apparatus claim, and it is talking about in the preamble
15 this function or whatever you want to call it, intended use or
16 function of providing decoded program data. And here the
17 Federal Circuit found that this language requires that the
18 apparatus must be actually capable of doing this decoding.
19 And I want to be clear, defendants in their briefs have
20 suggested that we're arguing that this CINV language means
21 that the formulations have to be actually used in order to
22 infringe. That's not what the claims require. That's not
23 what we're saying. We're just saying it has to be capable of
24 doing that. Whatever the formulation is, if we're going to
25 allege infringement of that formulation, that formulation has

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1 to be capable of being used to treat CINV in humans.

2 THE COURT: I dimly recall that you had the -- if you
3 try to put the actual use of it into the patent then the users
4 wind up being sued for patent infringement because they're
5 practicing the patent, and, so, that's why the patent drafter
6 stops short of saying, "and you use it."

7 MR. DITTMANN: Right.

8 THE COURT: So, they say it has to be capable of
9 being used that way.

10 MR. DITTMANN: So to be clear, these are formulation
11 claims that have this capability. You know, formulations, of
12 course, can be used for many different things, different
13 medical purposes. Here we're being very particular that it
14 has to have the capability of treating CINV. And this is
15 analogous, again, to this Vizio case where this
16 capability-type language in the preamble because it was a
17 fundamental characteristic of the invention, which we think is
18 the case here based on the prosecution's statements alone, we
19 think it is analogous, and, again, to briefly refer back to
20 the specification we went through a number of disclosures
21 showing, again, that this idea of reducing chemotherapy form
22 of emesis is a fundamental characteristic of what this
23 invention is all about. These are medicines for a particular
24 purpose.

25 THE COURT: Now, palonosetron has other potential

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1 uses, as well, such as the post-surgical, post-op application,
2 right?

3 MR. DITTMANN: There's certainly that. Medicines can
4 be used for a whole host of reasons. I know setrons were
5 investigated in the 1990s for anxiety and depression. So,
6 again, a formulation can be used for different purposes, and,
7 again, the inquiry -- we're not saying that in every case, you
8 know, the formulation claims have to have some sort of a
9 capable use characteristic, but in this case under these
10 facts -- forget about general principles; apply the facts, and
11 under these facts the limitation is clearly serving to
12 circumscribe the claim.

13 And that's all I had at least for now. I would like to
14 save some time for rebuttal, and I appreciate your patience,
15 your Honor.

16 THE COURT: Fine. Let's take our five-minute recess
17 now. Thank you, Mr. Dittmann.

18 MR. DITTMANN: Thank you.

19 (Brief Recess.)

20 THE COURT: And Mr. Wong.

21 MR. WONG: Your Honor. May it please the Court.
22 Good afternoon, Your Honor. It is good to see you again. My
23 name is Jovial Wong from Winston and Strawn, and I am counsel
24 for the Teva defendants. I'll also be making this argument on
25 behalf of Sandoz and DRL.

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1 Your Honor, this is just a preview of what I'll be
2 addressing today, but, certainly, if you have any questions
3 along the way feel free to ask them, and I'll answer them as
4 they come up.

5 By now I think you know where the parties stand, so on
6 the background issues I'll try to be brief. The preamble
7 language that is disputed by the parties is not a limitation
8 of a claimed palonosetron formulation. And the analysis in
9 our view is really quite simple. As I will explain, the law
10 of the Federal Circuit is that in general preamble terms are
11 not limiting. And more specifically, for terms of intended
12 use like we have here, preambles are not limiting. That is
13 the starting point that we have here, and plaintiffs have an
14 uphill battle to show otherwise.

15 Now, this general rule that preambles aren't limiting
16 is not a blanket rule that applies to every preamble term,
17 and, certainly, we're not arguing that. We agree that the
18 rule is applied on a case-by-case basis, and that's what we
19 have done here. And after considering all the evidence it is
20 clear that plaintiffs's reliance on two exceptions don't meet
21 the requirements that transforms the disputed preamble
22 language into a limitation.

23 I just want to take a minute to set the proper context
24 that we have here for the '219 patent. And, Your Honor, I
25 think this will help you in your understanding of the disputed

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1 preamble language. As counsel explained, this is Claim 1 from
2 the '219 patent. It starts with the preamble, and it says, "a
3 pharmaceutical single-use unit-dose formulation." The
4 preamble then has the intended use, which is at issue here.
5 "For intravenous administration to a human to reduce the
6 likelihood of cancer chemotherapy-induced nausea and vomiting;
7 i.e., CINV." We have highlighted this intended use, the
8 disputed preamble language in red. It doesn't show up too
9 well, but, certainly, in the slides I think it is more
10 apparent.

11 Now, to take a step back, the '219 patent is all about
12 palonosetron formulations. More specifically, as you recall,
13 the alleged discovery was that the inventors came up with a
14 way to make a palonosetron formulation more stable than what
15 was already known in the prior art for intravenous
16 palonosetron formulations. So, this is reflected here in
17 Claim 1. As you see, the claim is a pharmaceutical single-use
18 unit-dose formulation. It lists out several formulation
19 specifics in the body, including a 5 milliliter solution, 0.25
20 milligrams of palonosetron and, also, various concentrations
21 of excipients like EDTA and mannitol. And at the end the
22 result of all of this is that the formulation is stable for 24
23 months when stored at room temperature. That is the essence
24 or central aspect of the alleged invention of the '219 patent.
25 Using it to treat emesis or CINV is not the central aspect,

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1 and because the use of palonosetron as an antiemetic was
2 already known in the prior art.

3 Your Honor, I hope all of this sounds familiar because
4 this is exactly what we discussed the last time we were here
5 for claim construction. As you recall from those Markman
6 proceedings, the disputed issue was the plain and ordinary
7 meaning of the term "pharmaceutically stable." As you can see
8 here in Claim 1 of the '724 patent it recites a
9 "pharmaceutically stable intravenous solution." And the
10 parties, both plaintiffs and defendants, we went on and on in
11 argument in our papers as to why this improved stability was
12 so important to the formulation and why it was a core aspect
13 of the invention, the core invention. Well, your Honor, here
14 we have the two claims, the '219 patent and the '724 patent.

15 THE COURT: Not so fast.

16 MR. WONG: The core invention of the previous
17 patents, such as the '724, the '725, and the '424 patents is
18 the same as the core invention in the '219 patent. It is
19 improved stability formulations. And this makes sense because
20 all the patents at issue here, all four, they share the nearly
21 identical specifications, nearly identical set of inventors,
22 and they all claim priority back to the same provisional
23 application.

24 THE COURT: But I see a tonicifying effective amount
25 of mannitol in your Claim 1 of the '724 patent.

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1 MR. WONG: Right. And in --

2 THE COURT: And in the preamble it says
3 "intravenous."

4 MR. WONG: Right. Right. So, in general, they all
5 relate to palonosetron formulations and solutions, and as
6 counsel explained there are different iterations of what is
7 claimed, but, again, it is all formulations that have improved
8 stability over the prior art as the point there.

9 And if you compare the claims specifically, you're
10 right, they are very similar. Claim 1 of the '219 patent goes
11 to a formulation. Same with Claim 1 of the '724 patent; it's
12 a solution, a formulation. They both list out formulation
13 specifics like excipients, concentrations, and they all have a
14 stability aspect to it. In the claims of the '219 patent it
15 is expressly listed out that the formulation is stable at 24
16 months at room temperature, and in Claim 1 of the '724 patent
17 they have the term "pharmaceutically stable."

18 Now, each --

19 THE COURT: But, you know, "pharmaceutically stable"
20 was a claim limitation, even though it was in the preamble of
21 that '724 Claim 1, right?

22 MR. WONG: Right. Right. And plaintiffs have
23 alleged that we have been inconsistent in our preamble and
24 treatment of preamble language. I have a slide on that to
25 address it. Basically, terms of structure, terms that add

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1 essential structure and modify the solution, such as
2 "pharmaceutically stable," such as "intravenous" in the '724
3 patent, we readily agree that those are limitations on the
4 claim because they provide structure to the claim.

5 Similarly, in the '219 patent you have "pharmaceutical
6 single-use unit-dose formulation," and the parties don't
7 dispute that that adds essential structure to the formulation
8 that renders it a limitation.

9 Each claim also has a '724 patent, and in the '219
10 patent they also have an intended use in the preamble. We
11 know what the intended use is for the '219 patent; that's what
12 we're disputing. The '724 patent claims, along with those of
13 the other patents, recite "for reducing emesis" or "reducing
14 the likelihood of emesis." It is another intended use in the
15 preamble, and we have been consistent the whole time through.
16 We say it is that intended use is not limiting here, and it is
17 also not limiting for the previous patents. We have always
18 been consistent, and our experts have taken that same
19 position.

20 And I'll explain why the fact that both claims have an
21 intended use is important. But moving on, so, as you know,
22 what we had before you is whether the intended use language of
23 the preamble is a limitation of the '219 claims. We say that
24 it is not per the general rule of the Federal Circuit.
25 Plaintiffs say that it is, and they rely on only two

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1 exceptions to that general rule.

2 And you asked this question, plaintiffs addressed it.

3 But why does the disputed preamble language matter? Your

4 Honor, you asked this question with regard to

5 "pharmaceutically stable." We thought you might be wondering

6 the same about this term after reading the briefs. The answer

7 is the same as last time. Plaintiffs are taking the

8 opportunity here at Markman to add in another limitation to

9 try to save their claims from being invalidated. Before they

10 took a narrow interpretation of the term "pharmaceutically

11 stable," and they said it had to mean 24 months at room

12 temperature, again, to save -- to protect their claims from an

13 obviousness or anticipation attack.

14 Here they're trying to say that the intended use, which

15 is disputed here, is another limitation of the claims, and,

16 your Honor, it matters. If these terms are limiting, as

17 plaintiffs contend, and we think that's contrary to the law,

18 it adds another limitation that we as defendants have to deal

19 with with respect to our defenses of obviousness and

20 anticipation. And, you know, we have had our experts take

21 alternate positions with the prior expert discovery session

22 and now in this current expert discovery phase. And, so, they

23 interpret the claims as invalid whether or not the preamble is

24 a limitation waiting for further instruction from the Court.

25 So, plaintiffs's reference to --

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1 THE COURT: Wait a minute. So, plaintiffs to say
2 today they don't know why you think this Markman dispute has
3 to be decided, you're saying it goes to our defenses of
4 obviousness and anticipation?

5 MR. WONG: Correct. That's exactly right. And we're
6 surprised that plaintiffs contend that they're confused about
7 our positions. We have been clear the whole time. In all of
8 our expert reports our experts have said the claims are
9 invalid, even assuming that the limitation at issue, the
10 intended uses, are limitations. They have taken both
11 positions. It is not a limitation, it is a limitation, and in
12 either case they said it is not obvious -- it is obvious or
13 anticipated. We don't think that it is a limitation, and at
14 trial we don't think we should have to address that limitation
15 in our defenses.

16 But I was going to say plaintiffs flashed some excerpts
17 from our expert reports, and to be honest, your Honor, those
18 are taken out of context. Those are from portions of our
19 expert reports where they did assume it's a limitation. So,
20 that's why they had to address it in their experts's reports.

21 THE COURT: Or they did assume that it would be
22 construed to be a limitation.

23 MR. WONG: Correct, because we want to cover our
24 bases just in case the Court decides it in plaintiffs's favor.

25 So, now let's take a look at how the Federal Circuit

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1 actually treats the preamble of a claim. Your Honor,
2 generally the preamble does not limit the claim. That's right
3 from the Federal Circuit's case in Allen Engineering. All the
4 way since 2002 this has been the way the Federal Circuit deals
5 with preambles. And specifically, the Federal Circuit has
6 said, "a preamble limits the invention if it recites essential
7 structure or steps, or if it is necessary to give life,
8 meaning, and vitality to the claim."

9 If a preamble term doesn't do any of this then it is
10 not limiting per the Federal Circuit's general rule. And this
11 is the general rule that the Federal Circuit has used since
12 2002 when it handed down its Catalina Marketing V Coolsavings
13 case. Your Honor, that is a seminal case on preamble
14 interpretation. It is cited by all the Federal Circuit cases
15 since 2002, and what it is telling you, your Honor, is that
16 plaintiffs's briefs never affirmatively rely on Catalina
17 Marketing to support their position because it doesn't. And
18 the logic behind the rule that preambles are not limiting
19 makes sense. A preamble, as the name suggests, is just the
20 introductory part of the claim, right? It provides a general
21 gist of what the claimed invention is, whether it is a
22 compound, a formulation, a process, a method.

23 In contrast, the body of the claim, which is what
24 follows a preamble, is really where the Patent Office wants
25 the inventor to define the metes and bounds of the invention

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1 they claimed. Here the body of the claim has all the specific
2 ingredients that make the palonosetron formulation stable.

3 So, how do you determine whether the preamble recites
4 essential structure or gives meaning to the claim? The
5 Federal Circuit says look at the body of the claim. Here
6 again it is Claim 1. In Catalina Marketing at 809 the Federal
7 Circuit says, "The preamble is generally not limiting when the
8 claim body describes a structurally complete invention, such
9 that deletion of the preamble phrase does not affect the
10 structure or steps of the claimed invention." Your Honor,
11 that is exactly what we have here in Claim 1 of the '219
12 patent.

13 Again, the preamble starts with "a pharmaceutical
14 single-use unit-dose formulation," and then it continues with
15 the intended use. The body of the claim that follows lists
16 all the formulation specifics. So, the body of the claim,
17 plus these structural terms in the preamble "pharmaceutical
18 single-use unit-dose formulation," which everyone agrees is
19 limiting, together they define a structurally complete
20 invention. "A stable palonosetron formulation that is a core
21 invention." And we know it is structurally complete, your
22 Honor, because look what happens when you remove the intended
23 use. When you remove the disputed preamble language, which is
24 shown in this next Slide 10, you end up with the same thing.
25 "A stable palonosetron formulation that is a core invention."

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1 Nothing changes. You still have everything you need to define
2 a formulation that is stable at 24 months when stored at room
3 temperature.

4 Your Honor, the point here is that the intended use
5 that is in the preamble is unnecessary. It is not essential
6 to the claims, and if that is the case, the Federal Circuit
7 says it is not limiting.

8 THE COURT: What about the intravenous aspect?

9 MR. WONG: Right. Right. And I'll get to that.

10 THE COURT: I mean, I really see this as two phrases,
11 I must say. "For intravenous administration to a human" is
12 one phrase.

13 MR. WONG: Right.

14 THE COURT: And then "to reduce the likelihood of
15 cancer chemotherapy-induced nausea and vomiting" is a second
16 phrase.

17 MR. WONG: Right.

18 THE COURT: I think that each of you are addressing
19 your arguments to each phrase. You're not just lumping them
20 together. Mr. Dittmann certainly did. So I'm trying to hear
21 it that way.

22 MR. WONG: Right. And I will address both of these
23 phrases of the disputed preamble individually, but our
24 position is that both phrases, all of the disputed preamble
25 language is not limiting, and I'll show you why.

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1 So, here the point is that the claims without the
2 intended use provides a structurally complete invention. That
3 shows that the intended use is not necessary. And
4 specifically with respect to intended uses terms, intended use
5 terms in the preamble that we have here, the Federal Circuit
6 is very clear that they are generally not limiting. This is
7 from the Catalina Marketing case, again, and there the
8 preamble term at issue was an intended use. The phrase -- and
9 I'll show you later -- the phrase was "a system for
10 controlling the selection and dispensing of product
11 coupons..." and it goes on. So, it had a structure part, and
12 it had an intended use.

13 And it is a very narrow limitation that the Federal
14 Circuit has a very narrow exception that the Federal Circuit
15 has allowed for intended use specifically. And in all of
16 their briefing plaintiffs cite only two cases, and including
17 our cases that we have cited there are only two cases that
18 have been cited to the Court that have found intended uses
19 limiting. That's the In Re: Stencil case and the GEV Nintendo
20 case.

21 THE COURT: What was first one?

22 MR. WONG: In Re: Stencil. While the preambles, they
23 were intended uses, and they were found limiting in those
24 cases, there was a clear antecedent basis exception that made
25 it limiting, and, Your Honor, as I'll explain, that just isn't

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1 the case here. There is no such --

2 THE COURT: You're going too fast. I'm not getting
3 it.

4 MR. WONG: Right. So...

5 THE COURT: I'm your audience.

6 MR. WONG: My point here is that intended uses are --

7 THE COURT: There was a clear and what?

8 MR. WONG: Antecedent basis exception. It was a
9 clear exception in those two cases. That is not here. And,
10 so, that is why our intended use position here is that it is
11 not limiting because the same exception doesn't apply here to
12 make it limiting.

13 THE COURT: And you just cited the two cases where
14 you saw that uses or benefits in the preamble?

15 MR. WONG: Right. And those are the only two cases
16 among all the cases on preamble limitations where intended
17 uses -- or the issue of intended uses in preambles was up for
18 determination whether or not it is limiting or not.

19 THE COURT: Would that be without resort to the
20 prosecution history, those two cases?

21 MR. WONG: Exactly. I think including the
22 prosecution history, all the cases for the most part say that
23 intended uses are not limiting. These are the only two cases
24 that say it was limiting, and there was a clear antecedent
25 basis exception in both of those two cases.

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1 So, in addition to looking to see whether the disputed
2 preamble language adds essential structure, the inventors's
3 own statements during the prosecution are dispositive on this
4 issue, your Honor, despite what plaintiffs's counsel has
5 suggested.

6 Plaintiffs rely heavily on the prosecution history of
7 the '724 patent, '725 patent, the '424 patents in their
8 briefing, and the Federal Circuit certainly allows this when
9 interpreting the claims of the '219 patent. But, your Honor,
10 they failed to address and take on what are the most important
11 statements. And, again, before we get there I'll go back to
12 the similarities between the claims. Both the claims of the
13 '724 patent and the claims of the '219 patent have this
14 intended use in the preamble.

15 THE COURT: Roughly.

16 MR. WONG: Roughly. And according to -- they're both
17 intended uses; that's not disputed.

18 THE COURT: Right.

19 MR. WONG: And according to plaintiffs in their
20 briefing they said these are virtually identical intended
21 uses. That's right from both their opening brief and their
22 reply brief. And, so, how did the inventors treat the
23 intended use that was in the preambles of the '724 patent
24 before? They admitted that the intended use was not, was not
25 one of the limitations of the claimed palonosetron

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1 formulations, and they did this multiple times for each of the
2 claims of the '724, '725, and '424 patents that had the same
3 intended use in the preamble. And, so, here's a prosecution
4 history, all three of the patents went up to appeal at the
5 Patent Office, and here is what is required by the Patent
6 Office rules when you file your appeal brief. "Summary of
7 claimed subject matter:" should include, has to include, "a
8 concise explanation of the subject matter defined in each of
9 the independent claims involved in the appeal."

10 Now, plaintiffs suggest that, well, the preamble was
11 not at issue anymore by the time the cases got to appeal, but,
12 your Honor, we think that's a red herring.

13 THE COURT: Involved in the appeal.

14 MR. WONG: Right. Because bottom line is that the
15 Patent Office requires an explanation of what the claims are.
16 That's the bottom line. That comes right from --

17 THE COURT: So, you would say any claim that's
18 involved in the appeal, not just any claim term --

19 MR. WONG: Exactly. Exactly.

20 THE COURT: -- that's involved in the appeal.

21 MR. WONG: Here's the excerpt from the '724 patent
22 appeal brief. And it is the same thing for each of the '725
23 and '424 patents. Summary of the -- the subject matter --
24 again, it is the entire claim, not just the limitations. It
25 is entitled, "Summary of the claimed subject matter," which is

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1 the entire claim, not just specific limitations that are
2 involved in the appeal. And in this section the inventors
3 describe Claim 32, which eventually became Claim 1 of the '724
4 patent, the inventor said that "the claimed subject matter was
5 a formulation of palonosetron characterized by a combination
6 of ingredients, ingredient concentrations, and physical
7 characteristics." That's it. Those are all limitations in
8 the body of the claim. And to be even more clear, they said,
9 "The claimed formulation is limited by the following
10 features:"

11 Your Honor, none of the features -- they go on to list
12 one through six -- is the intended use for reducing emesis or
13 the likelihood of emesis. So, each time they went up on
14 appeal the inventors -- and it is the same inventors of the
15 '219 patent -- they admitted that the intended use in the
16 preamble of these claims are not limitations of the claims,
17 are not features of the claims. For the same reason here,
18 your Honor, the virtually identical intended use --

19 THE COURT: I still see the word "intravenous" there
20 because it is right in the listing of the '724 ingredients.

21 MR. WONG: Exactly. So, the claims of the '724
22 patent and the '219 patents are worded differently, and it is
23 not just semantics, which plaintiffs try to suggest. It is
24 actually claim drafting, and it makes a difference. But the
25 point here is that --

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1 THE COURT: One never knows.

2 MR. WONG: The virtually identical intended uses of
3 the disputed preamble language can't be a limitation because
4 they weren't before. We think that's dispositive, and
5 plaintiffs still haven't credibly shown why that shouldn't be
6 the case.

7 So, to address your point that these claims of the '724
8 patent embodied in an intravenous solution, that's absolutely
9 correct. That's right there in Claim 1 and point one, and
10 that's what the inventors rightfully said to the Patent
11 Office. But going back just two slides to compare it, that
12 has no bearing on the '219 patent claims, Your Honor. And in
13 the '724 patent the inventors affirmatively claimed an
14 intravenous solution, right? Intravenous was not part of the
15 intended use for reducing emesis or reducing the likelihood of
16 emesis.

17 THE COURT: What?

18 MR. WONG: If you see in Claim 1 it says, "a
19 pharmaceutically stable intravenous solution" and then the
20 intended use "for reducing emesis or reducing the likelihood
21 of emesis." So, they affirmatively claimed that their
22 solution there in Claim 1 of the '724 patent was an
23 intravenous solution. Here if you look at Claim 1 of the '219
24 patent, it is different. It claims "a pharmaceutical
25 single-use unit-dose formulation for intravenous

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1 administration," but "for intravenous administration" is not
2 affirmatively claimed; it is part of the intended use. And,
3 Your Honor, it makes a difference because the Federal Circuit
4 treats structural claims -- structural terms differently than
5 intended uses, as I reviewed.

6 THE COURT: I honestly don't think that the word "for
7 intravenous administration" is distinguishable from
8 "intravenous solution." It adds nothing. I mean, in that one
9 respect I probably don't see a distinction. If it is an
10 intravenous solution it connotes that you have to have a
11 certain structure parameter, but it also connotes that it is
12 going to go in a vein. So, maybe it is both.

13 MR. WONG: We don't dispute that, but for technical
14 patent claim drafting it does make a difference because it is
15 part of the intended use. Now, they could have drafted the
16 '219 claims to say "an intravenous formulation," and if they
17 did that, we wouldn't argue that that provides a central
18 structure to the formulation and that would be limiting, but,
19 your Honor, respectfully, our position here is that because
20 "for administration" is part of the intended use, the Federal
21 Circuit case law treats that differently and treats that not
22 as a limitation.

23 THE COURT: You mean the minute you have got the
24 preposition F-O-R everything after it is wiped out, unless an
25 exception applies?

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1 MR. WONG: That's our position.

2 THE COURT: Wipes it out from being a limitation?

3 MR. WONG: Right.

4 THE COURT: That sounds awfully literal to me, but go
5 ahead.

6 MR. WONG: Right. And it is a literal
7 interpretation, your Honor, but under the law that's how these
8 claims should be interpreted.

9 Now, so just wrapping up on the Federal Circuit law,
10 the fact that the claimed formulation without the intended use
11 is structurally complete, and, number two, the fact that the
12 inventors pretty much admitted this to the Patent Office we
13 think that that shows that the preamble language that's in
14 dispute is not limiting. It is consistent with the Federal
15 Circuit law, the general rule that these kind of intended use
16 terms are not limiting.

17 THE COURT: How about the fact that there was
18 actually an amendment to the part of the preamble '219
19 language that took out the word "prevent" this CINV and
20 replaced it with "to reduce the likelihood." That featured in
21 the prosecution history of this '219 patent, right?

22 MR. WONG: That was made in the prosecution history
23 not of the '219 patent, but of the parent patents, and we have
24 slides on that. We'll address that. Your Honor, under
25 Catalina Marketing, which requires that the term be

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1 distinguished from the prior art, not just to overcome a 112
2 rejection, we think that is not enough under the current
3 controlling case law to apply.

4 But just to kind of address your point on the two parts
5 of the disputed preamble language, one part is "for
6 intravenous administration," the other part is "to reduce the
7 likelihood of CINV." Again, our position is that both parts
8 of the disputed preamble are not limiting, but, certainly, if
9 your Honor thinks that plaintiffs have shown enough evidence
10 to say that the "for administration" part is limiting their
11 evidence on the latter part "for reducing CINV," certainly, we
12 think that is not limiting, and I'll show you why that is the
13 case.

14 THE COURT: I'll follow you.

15 MR. WONG: So with respect to the two exceptions,
16 and, again, the burden is on plaintiffs to show that these two
17 exceptions apply, neither of them apply in our case. That's
18 because the exceptions are very limited according to the
19 Federal Circuit, and they require specific and unmistakable
20 reliance to show that the intended uses are limiting. Your
21 Honor, we think it is a high burden and plaintiffs's evidence
22 is insufficient.

23 First --

24 THE COURT: I wonder what the reason is behind that
25 general rule, but I'll have to study Catalina Marketing.

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1 Go ahead.

2 MR. WONG: Actually, Catalina Marketing does make
3 some comments -- the Federal Circuit does explain why in
4 general preamble phrases that have intended uses aren't
5 limiting, and I have a slide on that. I'll get to that later.
6 It is because patentability in general is based on the
7 structure of the claims, not the intended use. That's why
8 intended use is especially for composition claims like we have
9 here are not limiting.

10 THE COURT: Okay.

11 MR. WONG: So, first, the antecedent basis exception.
12 From Catalina Marketing this exception requires reliance on
13 both a preamble and the claim body to the defined invention.
14 And here is a simple example of how this exception is applied
15 in all the Federal Circuit cases. So, take -- this is going
16 to be a hypothetical -- take the claim of a car for driving on
17 a highway, the car comprising A, B, and C. Okay. "A car for
18 driving on a highway." That's the preamble. Okay. "For
19 driving on a highway" is the intended use of the claimed car,
20 and that is generally not limiting; it is not a limitation of
21 the claims. It will be a limitation of the claims if there is
22 something else in the body of the claims, such as, "wherein
23 the highway is 20 miles long." That kind of statement, that
24 statement in the body, thus, makes the reference of "a
25 highway" in the preamble a limitation because that shows that

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1 the inventors used both the preamble and the claim body to
2 define their invention. That's how it works. That's the kind
3 of clear antecedent basis that all the Federal Circuit cases
4 require. And, Your Honor, that just isn't met here, and I'll
5 show you why for Claim 1.

6 So, here's Claim 1...

7 THE COURT: For driving on a highway at speeds
8 between 50 and 75 miles an hour. Where do you break it up?

9 MR. WONG: Unless there's something in the body of
10 the claim that references a term in the preamble, the case law
11 is clear that it is not limiting. Okay.

12 So, in my example --

13 THE COURT: None of it?

14 MR. WONG: -- the highway was 20 miles long, that
15 makes the highway a limitation of the claims.

16 THE COURT: Okay.

17 MR. WONG: So let's apply that analysis to Claim 1 of
18 the '219 patent. And I'm going to step through the disputed
19 preamble language step-by-step to show why this is not the
20 case.

21 So, the first part of the intended use is "for
22 intravenous administration." Okay? Your Honor, if you look
23 down to the rest of the claim, there is no reference to said
24 "intravenous administration" or anything like it.

25 THE COURT: That's true.

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1 MR. WONG: That's just absolutely not there. In
2 other words, "for intravenous administration" does not provide
3 antecedent basis for anything in the claim.

4 I'm going to keep going.

5 The next part of the disputed preamble language is "to
6 a human." Again, there's no reference, there's nothing in the
7 rest of the claim "to a human." And, finally, "to reduce the
8 likelihood of CINV." There's nothing in the rest of the claim
9 that references CINV, reduction of the likelihood, nothing
10 like that. And that's what the antecedent basis exception
11 requires. And it is not surprising because the body of the
12 claim are all stability terms. They're all what is required
13 to make the palonosetron formulation stable.

14 THE COURT: Well, there's also a therapeutic dosage.

15 MR. WONG: Right. That's just the amount of
16 palonosetron in the formulation. And, your Honor, with
17 respect to the specification they said that low
18 concentrations, low doses of palonosetron was important to
19 make it stable because it is all about stability. It
20 certainly doesn't say 0.25 milligrams to reduce the likelihood
21 of CINV. And, in fact, as you read the specification, there's
22 nothing in the specification regarding clinical trials or
23 showing that 0.25 milligrams is the effective dose for CINV.

24 THE COURT: Well, they assert it in the
25 specification. They say, surprisingly, we found that these

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1 low doses are still effective for this therapeutic purpose.

2 MR. WONG: Right.

3 THE COURT: But then there's no lab tests.

4 MR. WONG: It is unsupported, your Honor. And more
5 specifically, it was already known in the prior art that
6 palonosetron was an effective antiemetic, so although they say
7 that one statement, the rest of the specification is all about
8 stability, they supplied no data to show that they actually
9 discovered that, and that is the basis of our written
10 description requirement -- our defense for written description
11 for these claims. Because there was no disclosure in the
12 specification to support that -- to support this intended use,
13 to be frank.

14 THE COURT: So, even if you had this intended use as
15 a claim limitation you would still have your written
16 description defenses, which you have said?

17 MR. WONG: Exactly. Specifically because it is a
18 limitation, we think there's no support. If you find that it
19 is a limitation we think there's no support on it. That's an
20 additional defense that we'll have at trial.

21 So, again, because there's no antecedent basis provided
22 by anything in the disputed preamble language we think that
23 the intended use language is not a limitation of the claims.

24 Now, plaintiffs make the argument that we parsed the
25 preamble arbitrarily and without rational basis, and some

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1 cases agree that preamble terms are limiting and other cases
2 are saying that they are not limiting.

3 Your Honor, this is not the case at all. Our reading
4 of the preamble is grounded in a rational basis, grounded in
5 Federal Circuit precedence. The preamble can be divided as
6 follows: You first have the structural terms, which is --
7 that's in green. "A pharmaceutical single-use, unit-dose
8 formulation." We know the formulation is a limitation because
9 it provides direct antecedent basis for "said formulation"
10 later in the claims. There's no dispute there.

11 The terms "pharmaceutical single-use unit-dose" are
12 structural terms that add essential structures to what the
13 formulation is.

14 THE COURT: Well, your adversary points out
15 "single-use."

16 MR. WONG: Right.

17 THE COURT: Says you're only going to use it once.

18 MR. WONG: Right. And, Your Honor, to address that
19 point, this is the first time we have been hearing about this
20 in their briefs for plaintiffs to come up with a reason why it
21 involves a use. The fact of the matter is --

22 THE COURT: The word "use" is right there.

23 MR. WONG: The fact of the matter is "pharmaceutical
24 single-use unit-dose" doesn't relate to how it is used. It
25 relates to the formulation -- how the formulation is packaged

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1 and supplied. Our experts put in expert reports on this
2 limitation giving that exact same definition. Their experts
3 came back with expert reports that didn't even address it.
4 Didn't even dispute it. So, the definition that "single-use
5 unit-dose formulation" adds use is wrong. Our experts have
6 said it is the packaging -- it is how the formulation is
7 packaged and supplied. That's unrebutted in expert discovery.

8 THE COURT: Who are you going to dose this unit to?

9 MR. WONG: You certainly give --

10 THE COURT: A human.

11 MR. WONG: Right. You certainly give it to patients.

12 THE COURT: Not a cat.

13 MR. WONG: That's right. For all intents and
14 purposes the specification is about giving it to humans. But
15 the fact is the claims don't require that. The claims say
16 only in the intended use. There's no "human" limitation in
17 the claims. The "pharmaceutical single-use unit-dose" portion
18 is structural. It is not use. And their experts have not
19 contested that.

20 THE COURT: You know, it is odd. You seek to erase
21 this language, and then having erased it, you're going to
22 attack the patent as not being specific enough. I don't get
23 it.

24 But go ahead.

25 MR. WONG: We're only attacking the patent because it

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1 is not specific enough if this is -- if the intended use is a
2 claim limitation.

3 THE COURT: Precisely. It is a catch-22. Judge,
4 erase it, and then once it is erased it is not there, so the
5 patent isn't sufficiently specific on these points.

6 MR. WONG: Right. That's one reason why we say it
7 shouldn't be a limitation because it is not supported.

8 THE COURT: Well, that's a different argument. Right
9 now you're using a technical one, which is if it says "for"
10 then it is out. Read it out, unless some exception applies.

11 MR. WONG: Exactly. That's what our position is.

12 THE COURT: Okay.

13 MR. WONG: And plaintiffs have alleged that we have
14 been inconsistent in our way of treating preamble limitations.
15 They have referred to our agreeing that limitations
16 "pharmaceutically stable," "intravenous," "isotonic" in the
17 '724 patent claims are limitations, and here we say that -- we
18 definitely agree they're limitations because they provide
19 essential structure. They were affirmatively claimed. Here
20 all we're saying is that the intended use does not provide
21 essential structure, as I have shown. It is a structurally
22 complete intention even without the intended use. And even if
23 that is what the formulation that is claimed is used for the
24 Federal Circuit says that is not enough to make it a
25 limitation. This is from the Marrin case that we cited in our

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1 brief.

2 THE COURT: So, if it modifies a noun, if it modifies
3 a subject in the sentence then it is structural. But if it
4 modifies --

5 MR. WONG: It is actually just being capable of
6 performing that function. It is an intended use. It doesn't
7 directly modify formulation, which is our point.

8 THE COURT: "Administration" is a functional word,
9 and "to reduce" is the form of a verb, whereas "formulation"
10 is just a subject noun. If you're saying that grammar rules
11 here I'm going to be surprised, but that's, basically, what
12 you're saying.

13 Go ahead.

14 MR. WONG: According to the Federal Circuit that's
15 how you treat intended uses when they are in the preamble.

16 Here the Federal Circuit said the same thing. "The
17 mere fact that a structural term in the preamble," for
18 example, "formulation," the subject, the noun, "is part of the
19 claim does not mean that the preamble's statement of purpose;
20 i.e., the intended use or other description is also part of
21 the claim." So, structural terms like "formulation," "a
22 pharmaceutical single-use unit-dose formulation," which we
23 agree is the claim, the Federal Circuit says that's fine, but
24 for intended uses those are limitations.

25 At the end of the day the Federal Circuit treats

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1 structural terms differently from intended uses.

2 THE COURT: Does it matter what kind of a patent it
3 is? I mean, we have what we call "product patents" and then
4 we have "method patents." Some other kinds of patents.

5 MR. WONG: Right. And it does matter. Here we have
6 product patents, composition claims, intended uses aren't
7 limiting. For methods of using it, certainly, they can be
8 limiting.

9 Another argument in here is the argument that you
10 brought up is a difference between "for intravenous
11 administration" and it is providing antecedent basis for the
12 term "isotonic." And here we have "for intravenous
13 administration" in the preamble and "isotonic" in the body of
14 the claim.

15 Respectfully, your Honor, this is just not how the
16 antecedent basis exception works under Federal Circuit cases.
17 This is an apples-to-oranges comparison. You need something
18 specific. You need a reference to said "intravenous
19 administration." You need the term like "the isotonic
20 solution" in the preamble in order for it to match up. That
21 doesn't do it here, nor does "isotonic" need clarification, as
22 the plaintiffs suggested in their briefs. The parties
23 agreed -- we agreed during the last round that "isotonic" has
24 a plain stand-alone meaning. That's not disputed. And during
25 discovery experts have not disputed the meaning of "isotonic."

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1 THE COURT: Which means it is associated inexorably
2 with an intravenous use.

3 MR. WONG: That might be how the specification in its
4 full disclosure describes different kinds of formulations,
5 but, your Honor, in the claims the only limitation that you
6 need is that it be isotonic. It doesn't need to be an
7 intravenous solution literally under the claims. And it is
8 for intravenous administration, but it is not an intravenous
9 formulation when looking at the claims. And you might subsume
10 the same thing with the term "isotonic," but with regard to
11 the question does it have to be intravenous, under the claims
12 of the '219 patent, it doesn't have to be.

13 The American Medical Systems case cited by the Federal
14 Circuit says the same thing. "No antecedent basis where the
15 preamble term did not provide context essential to
16 understanding the meaning of the term in the body of the
17 claim." "Isotonic" or "for intravenous administration" does
18 not provide essential context for "isotonic" because none is
19 needed. "Isotonic" is a stand-alone term that is well
20 understood.

21 So, again, for the antecedent basis exception all the
22 plaintiffs's evidence we think is insufficient to transform
23 the disputed preamble language into a limitation, including
24 both parts, the "for administration" part, as well as the
25 "CINV" part. And as your Honor acknowledged, while "for

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1 intravenous" -- if you decide that "for intravenous
2 administration" is limiting we, of course, disagree, but as
3 far as the antecedent basis exception plaintiffs have not
4 brought forth any evidence to show that the reducing the
5 likelihood of CINV has antecedent basis for anything in the
6 claims. That shouldn't be a limitation.

7 THE COURT: I follow your argument. I just follow in
8 the sense that you can understand that there might be
9 distinctions between these phrases that could be made, which
10 you don't agree with. Right?

11 MR. WONG: Your Honor, the second exception is the
12 prosecution history exception.

13 THE COURT: Right.

14 MR. WONG: We think that their evidence doesn't meet
15 the requirements, and this is the requirement, again, from
16 Catalina Marketing. The Federal Circuit required two things.
17 Clear reliance on a preamble during prosecution and
18 specifically to distinguish the claimed invention from the
19 prior art. That's clear. Plaintiffs --

20 THE COURT: So, not just that you had to give up
21 something during prosecution history in order to get your
22 patent, it is not like prosecution estoppel.

23 MR. WONG: Precisely. It matters whether it is to
24 distinguish prior art or whether it is just to overcome a
25 rejection like a 112 rejection. Under Catalina Marketing,

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1 which we think is controlling, you need to distinguish prior
2 art. That was never done for any reference in the prosecution
3 history for any patent.

4 So, let's start with what was discussed in the '219
5 patent, okay? As plaintiffs's counsel suggested, it was very
6 brief. Only two references were raised by the examiner. The
7 CDER reference and the Baroni reference. But neither
8 reference was distinguished from the claimed invention and
9 certainly not by relying on the CINV part or any part of the
10 disputed preamble language. Instead, the inventors overcame
11 the art based on a technicality. They said that it came too
12 late in time, and it was published only after the filing date,
13 and that is what is shown here in the prosecution history.
14 The CDER publication does not qualify as prior art. It made
15 the same representation with regard to the Baroni publication.

16 Now, plaintiffs in their argument they raise the
17 examiner -- the interview summary with the examiner. And they
18 suggest that statements made by patent counsel, Mr. Sullivan,
19 suggest that the CINV part of the '219 claims is a limitation.
20 But, again, your Honor, closer examination of the prosecution
21 history shows that's not the case. Here's the entire examiner
22 interview. I think plaintiffs just showed you the top
23 portion. And in the entire interview they talk about three
24 topics, okay? Plaintiffs just discuss the first topic.

25 So, first the examiner discussed the claims themselves,

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1 not the prior art, and found it strange that there was no pH
2 limitation in the current claims because there was a pH
3 limitation in the preceding claims. And you see that right
4 here in the beginning. "The examiner discussed with
5 Mr. Sullivan the lack of a pH limitation in the claims."
6 Okay? In response Mr. Sullivan highlighted, and, actually,
7 made kind of a self-serving statement to say here are the
8 limitations, including CINV at the bottom.

9 THE COURT: I don't understand what the lack of pH
10 limitation would present as a problem, but go ahead.

11 MR. WONG: I actually don't either. It is a very
12 sparse interview summary. We certainly don't think it meets
13 the clear and unmistakable reliance that is necessary.

14 But what is telling is Mr. Sullivan's arguments were
15 not to distinguish the prior art, and even if it was, it
16 wasn't -- there was no clear and unmistakable reliance on the
17 CINV part specifically to distinguish the claimed invention.
18 That is what the Federal Circuit requires, and that is just
19 blatantly absent here.

20 Moreover, in the second and third topics that were
21 discussed that is where Mr. Sullivan distinguishes the claims
22 over the prior art, like Tang and the Berger reference. And
23 in each case Mr. Sullivan, as you see here, he doesn't rely on
24 the intended use of treating CINV as a point of distinction.
25 Instead, he distinguishes the prior art based on the

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1 formulation ingredients and concentrations like inventors have
2 done throughout the prosecution history.

3 THE COURT: Well, I mean in the middle of it here is
4 the applicant's attorney pointing out that Tang's data
5 indicated that only a pretty high-dose of this active
6 ingredient palonosetron significantly decreased the incidence
7 of vomiting, and the requirement for rescue antiemetics, and,
8 so, they're talking about comparing the necessary dosage for
9 that use in comparing the current pending application and the
10 Tang reference.

11 MR. WONG: Correct. And that's because there was, as
12 you know from the body of the claim, there's a specific dosage
13 requirement of 0.25 milligrams, and the discussion there is
14 just to say that they are different; the claims are different
15 in that respect. It doesn't say that the intended use for
16 treating CINV is a point that is different from the prior art.

17 THE COURT: Well, they're talking, though, about how
18 the 0.25 milligram dose described in these claims is much
19 lower -- in other words, Tang's dose to get some results is
20 much higher. They are talking about the use of this claimed
21 drug, aren't they?

22 MR. WONG: We think they're talking about the dose
23 because it is a specific limitation of what makes -- of what
24 the formulation is. They are not talking about using it --
25 the differences between using it to treat CINV or PONV. And

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1 the Federal Circuit, respectfully, your Honor, they require
2 clear reliance, clear and unmistakable reliance on the
3 prosecution history to distinguish the claimed invention. We
4 just don't think that is here.

5 THE COURT: What if your preamble that you were
6 attacking has the capability of being antiemetic, rather than
7 being specific to CINV?

8 MR. WONG: We still think that is not -- that would
9 not be supported here. Your Honor, what would be supportive,
10 just to put out a hypothetical, is if Mr. Sullivan said our
11 claims go to treating -- using palonosetron formulations to
12 treat CINV or to treat antiemetics. The prior art is not used
13 for this use. That would be a clear and unmistakable reliance
14 on the prior art to distinguish their invention.

15 THE COURT: I don't necessarily agree. I'm trying to
16 make sense out of this, and I don't have a preconceived notion
17 about where I'm going, so this is a dialogue.

18 MR. WONG: Sure.

19 THE COURT: But they're not just talking about
20 dosages in the abstract. They are talking about antiemetic
21 usage and how the prior art, while it is an antiemetic, and so
22 is this claimed invention, they're distinguishable, the prior
23 art is distinguishable because of the significant difference
24 in dosage. You know, maybe they're all wrong about the prior
25 art, but that's what they're focusing on, and that discussion

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1 is, okay, you have got the prior art that uses all this huge
2 amount of stuff to get some antiemetic effect, and here is our
3 new claim that just claims a very minuscule amount of the
4 active ingredient, and we're getting -- we're talking about
5 antiemetic use.

6 MR. WONG: Right. I think what you said as far as
7 our claims claiming a minuscule amount a specific 0.25 dose
8 that is what Mr. Sullivan used to distinguish the claims.

9 Now the context might be in the sense of CINV or at
10 least Tang was talking about PONV and the claims are in CINV,
11 but that really wasn't the critical reliance that Mr. Sullivan
12 was relying on. He just said our dose is 0.25. The dose in
13 Tang is higher. And that is a distinction that they relied on
14 to overcome the prior art. It wasn't the fact that Tang
15 talked about PONV or -- and the present claims talk about CINV
16 as far as intended uses.

17 THE COURT: No, but I asked you the question: Well,
18 what if our claim language at issue said "antiemetic" rather
19 than "CINV," and you said your argument would be the same,
20 that it is not enough of a clear prosecution history
21 indication that the use -- that is in the preamble of the
22 disputed claim language is limiting, but I see this word
23 "antiemetics" right here in their discussion. So, it seems to
24 me they're not discussing dosage in a vacuum; they're
25 discussing dosage as it relates to being an antiemetic agent.

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1 MR. WONG: And, again, I think that is a context
2 certainly because that is -- you know that is what dosages
3 apply to, but the specific dosage that they claim in the
4 pending claims at the time of the '219 patent was
5 0.25 milligrams. They used that limitation to distinguish the
6 prior art. And, again, that is not one of the disputed
7 preamble terms, and that's why we're saying it is not
8 relevant. It doesn't meet what the Federal Circuit requires
9 as a clear and unmistakable reliance on the disputed preamble
10 language because that's not one of the terms.

11 THE COURT: Well, we also agree, don't we, that claim
12 limitations don't all have to be novel. You know, claim
13 limitations can have lots that's in the prior art just so long
14 as the patent examiner finds that the invention as a whole is
15 novel.

16 MR. WONG: Right. Certainly.

17 THE COURT: Okay. Go ahead with your argument.

18 MR. WONG: Okay. So, instead of relying on clear
19 statements in the prosecution history plaintiff's reliance on
20 the prosecution history really amounts to an apples-to-oranges
21 comparison. Again, it is the difference between "intravenous"
22 and "for intravenous administration." I won't belabor this
23 point, but, your Honor, we think that none of the cases that
24 plaintiffs cite allow the narrow prosecution history exception
25 to apply one as an apples-to-oranges comparison of the claim

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1 terms. Here the claim is "intravenous" in the previous
2 prosecution, and the claim that we have here, the claim term
3 here is "for intravenous administration."

4 THE COURT: Okay. Magic word being "for."

5 MR. WONG: Exactly. And the next slide I think is
6 instructive because it really clarifies what was going on at
7 the time they made the amendment to introduce "intravenous"
8 into the solution.

9 Plaintiffs are correct that they amended Claim 32 --
10 again, that's Claim 1 of the '724 patent -- to narrow it to
11 say "intravenous solutions," and they made the argument to the
12 Patent Office that that distinguishes the formulation from
13 oral formulations that were in the prior art. Again, that's
14 "intravenous," it is not "for intravenous administration."
15 But in the same amendment look at what they did to Claim 40.
16 Claim 40 had adapted "for intravenous administration," and
17 they deleted it. They couldn't argue that this limitation was
18 sufficient to overcome the prior art for oral formulations.
19 We think that's significant. They never used "for intravenous
20 administration" to distinguish the prior art. They couldn't.
21 They had to delete it and replace it with something
22 affirmative, like "intravenous solution."

23 For this reason, your Honor, this doesn't meet the
24 clear and unmistakable reliance that is required for the
25 prosecution history exception.

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1 Now, you brought this up earlier, your Honor.

2 Plaintiffs rely on the fact that "preventing" was deleted from
3 the preamble in the prosecution for the previous patents, such
4 as the '724 patent. Your Honor, we think that this is not
5 enough either.

6 First, it is important to put this in the right
7 context, Your Honor. Claims with absolute terms like
8 "preventing" or "curing" are routinely, as a matter of course,
9 rejected by the Patent Office, and they're rejected under
10 Section 112 because even with the best clinical data it is
11 virtually impossible to show that something works 100 percent
12 of the time in 100 percent of the people. The Patent Office
13 is more amenable to phrases like "reducing" or "treating,"
14 which is why they replaced "preventing" with "reducing the
15 likelihood of emesis."

16 So, the fact that the examiner made the plaintiffs
17 remove "preventing" in the preamble doesn't demonstrate at all
18 that this is a limitation. In fact, there was no argument
19 either way by the examiner or the applicant that this preamble
20 language was limiting. It was really only --

21 THE COURT: They would never talk about that, though,
22 unfortunately.

23 MR. WONG: Well, if there really was an issue of
24 whether or not the preamble is limiting, you would expect they
25 would have raised it. They didn't raise it at all. It was

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1 actually a form rejection; it comes down to being basically a
2 form rejection that the examiner made, and they would make in
3 any claim that had the word "prevent" in it.

4 THE COURT: Well, this distinction between whether
5 preamble language is or is not limiting, I don't think it is
6 something that the patent examiner or even the Patent Board of
7 Appeals gets into.

8 MR. WONG: I think --

9 THE COURT: I think it is case law borne, right?

10 MR. WONG: I think that is correct, Your Honor. I
11 think when we read the prosecution history there is certainly
12 nothing that says it is a limitation, and that's what the
13 prosecution history exception requires. Affirmative reliance
14 on the preamble during prosecution to show that it is
15 limiting, that's not the case here. Whether or not the Patent
16 Office generally treats it as limiting or not limiting we say
17 we think they generally treat it as non-limiting. It is just
18 not clear from prosecution history. There's no evidence that
19 anyone in the Patent Office treated it as limiting.

20 THE COURT: Is there anything in that handbook, you
21 know, the patent Examiner's Handbook that talks about
22 preambles and whether language in there is limiting or not?

23 MR. WONG: You know, I'm not sure.

24 THE COURT: This is just idle curiosity. You don't
25 have to answer.

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1 MR. WONG: I'm not sure. We didn't cite it in our
2 briefs. Plaintiffs didn't cite anything to the contrary.

3 Second, your Honor, to put this amendment in
4 perspective, the enablement rejection and the deletion of
5 "preventing" was made very early on in the prosecution
6 history. It was actually made in the first office action that
7 the examiner issued, and there they objected to the word
8 "preventing." That is in 2006, which, again, really shows
9 it's a form rejection that the examiner made.

10 THE COURT: And it is Section 112, as you say?

11 MR. WONG: That's right.

12 THE COURT: It is not an obviousness rejection?

13 MR. WONG: Correct.

14 THE COURT: It has nothing to do with distinguishing
15 the prior art?

16 MR. WONG: Precisely. After this initial rejection
17 there was three years of substantive prosecution back and
18 forth between the examiner and the inventors as to why the
19 claim should be patentable. All of that discussion, your
20 Honor, had to do with prior art that dealt with formulation
21 specifics, whether it is the EDTA, the mannitol, the
22 palonosetron concentrations. None of it had to do with the
23 preamble language. And at the end, your Honor, in 2010 -- we
24 already talked about this -- the inventors submitted their
25 appeal briefs, and they actually admitted that the preamble is

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1 not part -- was not part of the concise statement that they
2 needed to make when they described their claims.

3 Again, the last thing, your Honor --

4 THE COURT: Where is that?

5 MR. WONG: It is on the chart. It is that last
6 point, May 2010 when they submitted their appeal brief.

7 THE COURT: And what are they admitting there?

8 MR. WONG: When they were required to list out what
9 their claim features are, they listed out features one through
10 six. None of it included the intended use "for reducing
11 emesis."

12 THE COURT: That's where you started your argument.

13 MR. WONG: Exactly. Exactly.

14 So considering that timeline as a whole really, your
15 Honor, the fact that there was a preventing amendment early on
16 in the prosecution it doesn't amount to the clear reliance,
17 the unmistakable reliance on the prosecution history to make
18 the intended use limited. So, and that's what is required by
19 Catalina Marketing and all the rest of the cases that cite
20 that.

21 So, how do the plaintiffs side step the requirements of
22 Catalina Marketing? They rely on a single case Fantasy Sports
23 that plaintiffs's counsel discussed, but that is irrelevant
24 and distinguishable for many reasons. First, if not most
25 important, Fantasy Sports was issued by the Federal Circuit in

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1 April of 2002. Catalina Marketing issued in May 2002, and all
2 the cases since Catalina Marketing require for the prosecution
3 history exception that there is a clear reliance on the
4 preamble to distinguish the prior art. Not just overcoming a
5 112 rejection. That's our position there.

6 Second, even if Fantasy Sports was applicable, which we
7 don't think it is, plaintiffs's entire argument relies on a
8 single footnote, Footnote Number 3, which really is almost
9 passing dicta, and according to the footnote it says -- it
10 talks about the preamble, but focuses on the "computer"
11 limitation, and at the end of the day it is the "computer"
12 limitation that they found was a limiting part of the preamble
13 because it provided structure. It said nothing about the
14 intended use of "playing football based on actual football
15 games. "

16 This is what the original claim was in Fantasy Sports:
17 "An apparatus for playing football based on actual football
18 games..." The examiner put forth a 112 rejection saying
19 there's no support, there's no disclosure for apparatus, it is
20 too vague. So what they did -- and they overcame the 112
21 rejection -- is they replaced "apparatus" with "computer."
22 They didn't touch the intended use, and they made no argument
23 to say that it was limiting.

24 So, your Honor, if anything, if it is even applicable,
25 Fantasy Sports is also distinguishable from our situation

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1 because it doesn't stand for the proposition at all that the
2 intended use part of a preamble can be limiting.

3 At the end of the day applying what we think is the
4 appropriate controlling case law, it is clear that the
5 prosecution history exception does not apply.

6 Your Honor, just a couple final points to wrap up here.

7 Plaintiffs in the briefing suggested that our position
8 under the disputed preamble language is nonsensical. We
9 obviously disagree. The hypothetical example they posited is
10 a palonosetron formulation that had all the ingredients that
11 are in the body claims, all the formulation specifics, but
12 didn't have the intended use. It didn't have the ability to
13 treat CINV. Plaintiffs said that such a formulation would,
14 nonetheless, be covered by the claims under our reading of the
15 preamble language, and plaintiffs pointed out that that was
16 nonsensical. But, your Honor, far from being nonsensical,
17 that is exactly what patent law requires.

18 Again, there is no dispute that all the claims here in
19 the '219 patent they are all composition claims, a formulation
20 of palonosetron. And as composition claims Catalina Marketing
21 says, "...preambles describing the use of an invention
22 generally do not limit the claims because the patentability of
23 apparatus or composition claims depends on the claimed
24 structure not on the use or purpose of that structure." They
25 go on to say, "this means that a patent grants the right to

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1 exclude others from making...selling...the claimed apparatus
2 or composition for any use of that apparatus or composition."

3 THE COURT: So, you're saying that this is really in
4 there to benefit actually the patent holder, rather than to
5 penalize the patent holder, the idea that if you claim a
6 composition whether somebody uses it to fry an egg --

7 MR. WONG: Exactly.

8 THE COURT: -- or to go to the moon, the composition
9 is infringed.

10 MR. WONG: Exactly. And in our briefing we made the
11 argument saying that if our palonosetron formulations were
12 used for treating, I think it is arthritis or Alzheimer's,
13 they could still literally infringe the claims because all the
14 formulation specifics in the body of the claims were met, even
15 though the intended use was not met because it is not treating
16 CINV, it is treating something else like Alzheimer's, and
17 that's what the Federal Circuit has said. The bottom line is
18 that intended uses for composition claims don't really matter.
19 For method claims, yes.

20 THE COURT: I have seen, you know, a method of
21 treating a, you know, human for diphteria and that now we
22 found out that it can also be used for some other use and then
23 you get a different patent for that.

24 MR. WONG: Right. Right.

25 THE COURT: Because it is a method patent.

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1 MR. WONG: So for method claims the intended uses
2 that are recited in the preamble those are limiting on the
3 claims generally. Those are limiting on the method claims.

4 THE COURT: Oh, in method claims. Oh. Even if it is
5 just in the preamble?

6 MR. WONG: It is because it is essential to what the
7 method is. It is a general gist of what the method is, and it
8 provides essential structure or I think another thing they
9 said is that it provides essential steps, so it is a method
10 for treating something specifically. We're not dealing with
11 method claims here, we're dealing with composition claims. We
12 think the Federal Circuit intended uses for composition claims
13 aren't limitations based on what they say in Catalina
14 Marketing.

15 So, let's see how the Federal Circuit applied this to
16 Catalina Marketing claim specifically, and they're very
17 analogous to the '219 patent claims. The preamble has both a
18 structure and an intended use. Here in Catalina Marketing the
19 structure is "A system." It is here in green. The intended
20 use is "for controlling the selection and dispensing of the
21 product coupons..." and it goes on. But the Federal Circuit
22 found this use not limiting, and here's the rationale in the
23 last quote. "In this case the disputed preamble language does
24 not limit Claim 1 - an apparatus claim. To hold otherwise
25 would effectively impose a method limitation on an apparatus

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1 claim without justification."

2 Your Honor, this is precisely what plaintiffs are
3 asking you to do. Impose a method limitation on a formulation
4 claim without justification. We think that's improper under
5 clear Federal Circuit precedence, therefore, defendants
6 respectfully ask this Court to find that disputed preamble
7 language is not limiting in the claims of the '219 patent.

8 Thank you.

9 THE COURT: Okay. Thank you. If there's anything
10 that you absolutely must respond to I will let you briefly.

11 MR. DITTMANN: Thank you, Your Honor. I appreciate
12 it. If you can just bring up that slide that you just used
13 that would be great.

14 Just to make very clear, your Honor, this may be part
15 of the defendant's misconception about this written
16 description issue. We are not imposing a method limitation on
17 these claims. Like the Vizio case, which is an example of
18 intended use-type limitations requiring a capability of
19 structure to be capable of doing something that's what we're
20 saying, capable of treating CINV. We're not saying you have
21 to impose a method limitation, actually treat a patient for
22 CINV to satisfy the claims. That's not our argument. It has
23 to do with a capability of the accused structure. Whatever
24 the ingredients are in that accused structure is it capable of
25 treating CINV.

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1 More importantly, just briefly, I think that it seems
2 like we're pretty much mostly there on the I.V. language, as
3 your Honor correctly noted. We're really talking about rules
4 of grammar and magic words at this point. He made no attempt
5 to distinguish the meaning of these two phrases, which is
6 really what matters.

7 Moreover, the prosecution of the parent applications
8 that we went through, again, these terms, even if there was
9 some possible basis to say they're slightly different, which
10 we don't think there are, you still can rely on the parent
11 prosecution to find this limitation to apply.

12 And there was no response, your Honor, and I'll get to
13 the claim in a moment, you remember I showed you the body of
14 the claim has the word "isotonic." That's clearly a claim
15 limitation, and I showed you the prosecution history of the
16 parent application where it said when you talked about
17 isotonic in these claims it requires an intravenous
18 formulation. So, putting this preamble dispute aside about
19 grammar "for intravenous administration," if you look purely
20 at the word "isotonic" and you look at the prosecution
21 statements applying to that exact term an intravenous
22 formulation is required by these claims irrespective of the
23 preamble issue.

24 THE COURT: I think he said that nobody is going to
25 dispute that this composition that's claimed is intended to be

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1 an intravenous composition because of the word "isotonic" in
2 the precise enumerated listing of ingredients.

3 MR. DITTMANN: Right.

4 THE COURT: He said what we're objecting to is adding
5 the word "intravenous" as a limitation from the preamble
6 because it is not in the right phraseology because it is
7 phrased as a use there.

8 MR. DITTMANN: If defendants are willing to stipulate
9 that "intravenous formulation" comes in through the word
10 "isotonic" we're fine with that. There's no need for us
11 to belabor this dispute on preamble, so we're certainly fine with
12 that.

13 THE COURT: Now, if it were to be intracellular or
14 intramuscular would "isotonic" introduce an ambiguity? You
15 know, it might. We don't know sitting here.

16 MR. DITTMANN: I don't believe it would for purposes
17 of this case, your Honor, but, again, the prosecution history
18 answers that for us because it says when you use the word
19 "isotonic" we're talking about intravenous formulations. It
20 is clear. It takes that exact same language and says this is
21 what we mean, and you take the patentees at their word when
22 they make these sort of statements.

23 But I want to go back to this claim because, again, I
24 think one big fundamental understanding is there's an argument
25 about, well, unless the reference in the body of the claim

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1 matches to what's in the preamble it doesn't limit. Well,
2 defendants say that "single-use unit-dose" is a limitation of
3 this claim.

4 THE COURT: Is a limitation because it is structural.

5 MR. DITTMANN: I'm going to get to that in a minute.
6 But, first of all, I don't see that anywhere in this claim.
7 So their matching tests clearly can't be right. It says,
8 "said formulation." It doesn't say anything about single-use.
9 Doesn't say anything about unit-dose. It simply refers back
10 to "said formulation," which, again, the only context for that
11 is in the preamble. So we'll start from that premise.

12 But I do want to address, your Honor, the single-use
13 unit-dose argument, and I can provide you with these slides.
14 These are a couple slides I had just in case these issues came
15 up and you wanted to hear about them. But, again, going to
16 these statements about general principles that it is a rare
17 case that an intended use could limit a claim. Well, I want
18 to explain why this is such a case and defendants have
19 admitted that.

20 Again, the single-use unit-dose everyone agrees is a
21 limitation of the claims. This is an expert report from Dr.
22 Spilker, one of defendant's experts, who submitted this just
23 last month. So this is a report addressing this point we're
24 talking about today. And he says, single-use is if it is only
25 used once and then discarded. Use. He says, unit-dose means

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1 it has the amount of pharmaceutical ingredient customarily
2 used. Now, in this case if we go back to the claims we
3 already know the amount. The amount is 0.25 milligrams and --
4 0.25 milligrams and 5 milliliters, so it is a 5 milliliter
5 solution, and it is used once, and that's the amount that's
6 needed to treat the condition we're talking about. So, if
7 anything, Dr. Spilker's discussion of unit-dose ties in this
8 customary use idea of what are you using it for. We're using
9 it to treat cancer chemotherapy-induced nausea and vomiting.

10 So, again, point number one, defendants's matching test
11 fails for the claim language they admit is limiting. There's
12 nothing in here that ties single-use or unit-dose to the
13 bodies of the claim.

14 And number two single-use unit-dose --

15 THE COURT: What they're doing is they're looking at
16 it grammatically and saying the terms "single-use" and
17 "unit-dose" are used as adjectives to modify the noun
18 "formulation" as a subject, not an object of the sentence. It
19 is not a sentence. The whole thing is not a sentence. The
20 whole preamble is not a sentence.

21 MR. DITTMANN: The preamble is not a sentence, but
22 the preamble, we would submit, describes the formulation, and
23 let me explain why.

24 THE COURT: But they're saying these two adjectives
25 in front of the noun "formulation" don't have to be stripped

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1 off of the noun "formulation." "Said formulation" should pick
2 up the nouns that immediately previously modify them. And
3 you're saying, well, good, then why doesn't the word
4 "formulation" in the preamble also pick up all of the
5 dependent phrases that are attached at the other side of the
6 word "formulation."

7 MR. DITTMANN: If you want to get into rules of
8 grammar what this is, "for intravenous administration" is a
9 prepositional phrase that functions as an adjective. Look it
10 up in any grammar book. And the same applies to the rest of
11 this. So what we have here is a series of adjectives. And
12 they could have written this as single-use unit-dose,
13 intravenous, cancer chemotherapy-inducing treating -- you
14 know, it gets cumbersome after a while, and sometimes people
15 use different ways to explain the same concept. But, again,
16 we would submit that these are prepositional phrases that
17 function as adjectives, and it is made crystal clear through
18 the prosecution that these are time limitations. And if I may
19 go to, again, the '219 patent prosecution history where the
20 examiner was summarizing what was discussed because I do think
21 that's important. It doesn't get much clearer, your Honor,
22 than this. "Highlighted the limitations that were in the
23 claims." "Cancer chemotherapy-induced nausea and vomiting."
24 Your Honor, again, if we were attempting -- if a
25 patentee was attempting to say this is not a limitation of the

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1 claim and this matter to infringement, for example, they would
2 be the saying this is a representation, a clear representation
3 of what's in the claims. They couldn't be any clearer.

4 THE COURT: I understand, but what your adversary was
5 arguing was that the highlighting would have to be to
6 distinguish prior art, not to highlight for purposes of being
7 sufficiently clear, and what's the word, Section 112. I
8 always get "enablement" and "written description" mixed up
9 because to me they blend together. Written description, where
10 is the pH in there is what the examiner is asking, and you
11 say, well, we have got all this other stuff in there that
12 makes it sufficiently definite.

13 MR. DITTMANN: There's a couple things on that
14 because you raise a very good point that I wanted to address.
15 Catalina Marketing, if you read that decision, is just a
16 summary of previous decisions. It isn't some watermark case
17 that established a new rule of law. In that case they talked
18 about relying on the prosecution to distinguish the prior art
19 surely as a way that you can transform a preamble language
20 into a limitation. Fantasy Sports came out the same time. I
21 was the law clerk that worked on Fantasy Sports. I know the
22 case very well. Fantasy Sports, if you look at when the
23 petition for rehearing was denied, it was denied after
24 Catalina was issued, so if Catalina changed the law in any
25 respect the Federal Circuit would have addressed that.

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1 Putting that aside, Fantasy Sports could not be clearer
2 that it was reliance on preamble to overcome a 112 rejection.

3 THE COURT: A 112?

4 MR. DITTMANN: 112. Transform that into a claim
5 limitation. And, again, that's exactly what we have in our
6 case, and going back to this point about being clear, your
7 Honor, again, it doesn't get much clearer than the claims are
8 directed towards reducing emesis and reducing the likelihood
9 of emesis.

10 All defendants can point to is in some appeal brief
11 they didn't mention those words in the concise summary, which,
12 again, number one, doesn't have to address, as your Honor was
13 alluding to, doesn't have to address every single claim
14 element. It was discussing what was involved in that appeal.
15 This is crystal clear. Directed towards. They did it again.

16 THE COURT: And they're talking there about we're
17 going to talk about "reducing," rather than "preventing," and
18 we're watering down our language to "reducing" to satisfy your
19 overinclusiveness of, what is it, written description
20 objection.

21 MR. DITTMANN: Right. The applicants didn't agree
22 with the examiner, but they said let's -- we'll amend it to
23 make you happy to overcome this rejection.

24 Now, I also wanted to very briefly --

25 THE COURT: Go on and talk about Tang because I got

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1 quite focused on that --

2 MR. DITTMANN: Yes, I wanted to come back to that.

3 THE COURT: -- in that examiner interview.

4 MR. DITTMANN: So, again, it is an examiner
5 interview, and, again, we don't think it could be any clearer
6 that it is discussing prior art. If there was a mention in
7 the beginning of this summary record about what about the lack
8 of pH, you know, that could be the examiner is wondering,
9 well, wait a minute, how are you going to distinguish this
10 prior art if you don't have a pH limitation?

11 THE COURT: So, it could have been obviousness or
12 written description?

13 MR. DITTMANN: And, your Honor, when it says "prior
14 art discussed" that means they're talking about prior art, not
15 a written description or an enablement issue.

16 THE COURT: Where is the word "prior art"? Oh, okay
17 up there. Right.

18 MR. DITTMANN: So, very clear we're talking about
19 overcoming the prior art. Number one.

20 Number two, again, the statement couldn't be clearer.
21 There's no test of what may be the potential intent of
22 Mr. Sullivan -- and the counsel for defendants said maybe this
23 was a self-serving statement. That's irrelevant. What he
24 said is what you're stuck to. The patentee makes a
25 representation of what's in the claims. They're bound by it.

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1 And more to your point, your Honor, again, here they
2 highlighted this claim limitation "cancer chemotherapy-induced
3 nausea and vomiting" and discuss Tang in the context of PONV.

4 THE COURT: In other words, look, we are coming out
5 with something that addresses the cancer chemotherapy-induced
6 condition at a very low dosage and distinguishing it from the
7 post-op condition that has hitherto under Tang prior art
8 required a much higher dosage.

9 MR. DITTMANN: And, Your Honor, you'll hear a lot
10 about this when the parties are before you at trial.

11 THE COURT: But is that what they're talking about?

12 MR. DITTMAN: Yes, that is what they're saying.

13 THE COURT: They are distinguishing prior art?

14 MR. DITTMANN: They are distinguishing the Tang
15 reference on a number of grounds, one of which is this is a
16 PONV study, whereas we're talking about cancer chemotherapy
17 nausea and vomiting in our claims.

18 THE COURT: So, you disagree with defendants that it
19 is just a discussion about relative dosage amounts comparing
20 the applicant's application with Tang's higher dosage?

21 MR. DITTMANN: It certainly involved that discussion
22 of dosage amounts, but there is more than that reflected in
23 this interview summary record, but, again, I would submit that
24 this statement is enough. "Limitations that were in the
25 claims." It doesn't get any clearer than that.

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1 THE COURT: And I suppose then that as the patent
2 holder plaintiff in this case if somebody comes along and
3 wants to use a pharmaceutical composition for something other
4 than CINV you would agree that it is not covered by this '219
5 patent, it is not infringing of the '219 patent.

6 MR. DITTMANN: Are you talking about an actual
7 product that's being sold on the market?

8 THE COURT: I'm saying an FDA application. In other
9 words, let me turn it around. Defendant's next to last
10 argument was, well, the reason -- and the reason that Catalina
11 Marketing says that these usage phrases in the preamble to a
12 composition or apparatus patent are not generally considered
13 to be limitations is that if you've got a composition or an
14 apparatus then the patent holder for that gets it on the
15 composition and the apparatus, not on the use of it. And that
16 actually makes it a much broader patent territory covered by
17 that patent because regardless of how the would be infringer
18 would seek to use the thing they're still infringing because
19 they're infringing the composition without any use limitation
20 in the patent.

21 MR. DITTMANN: Let me --

22 THE COURT: So, you're willing to live with that,
23 right?

24 MR. DITTMANN: This is not a use limitation. Again,
25 this is a capability. So, in your hypothetical if someone was

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1 saying I have this palonosetron formulation, and I'm selling
2 it for some other indication, if what they're selling has the
3 capability, the amounts, the dosage amount the way it is
4 delivered, if it can treat CINV it infringes. It is a
5 capability.

6 THE COURT: Even if they're advertising it for some
7 other use?

8 MR. DITTMANN: Yes, because it is a composition
9 claim.

10 THE COURT: Or getting it approved by the FDA for
11 another use?

12 MR. DITTMANN: Again, there's no use limitation in
13 this patent. It is only a capability. It is capability. The
14 formulation has to be capable. Just like the Vizio case,
15 which I think is analogous that counsel didn't discuss, but it
16 is capable of being able to do something. All the structure
17 in the formulation has to be capable of treating CINV. If it
18 can't do that, it wouldn't be covered. But, again, it is not
19 a use limitation.

20 THE COURT: What if you have a method patent for a
21 pharmaceutical composition, and I have seen a lot of these
22 where the method says, the method of treating a patient
23 consisting of -- I never understand this. Getting a hold of
24 the following five ingredients and baking them three times and
25 distilling them and formulating them into a tablet, period.

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1 That's supposedly a method patent. But it has got all the
2 steps and ingredients for making the finished product. Could
3 a method patent such as that ever be claimed to infringe a
4 composition patent such as this '219 patent if the result of
5 practicing the method then would be capable of having this
6 therapeutic effect. In other words, can somebody claiming a
7 method actually infringe a composition patent?

8 MR. DITTMANN: Well, I think in your hypothetical,
9 your Honor, a method of manufacturing patent if in making the
10 composition that's covered by our claims if they followed
11 those steps that you laid out they would infringe both the
12 method of making it, which is one thing, and then there's also
13 they would then infringe the composition because what they
14 ended up with after they have copied the method of the
15 manufacturing is the same product that we claim in our patent.

16 THE COURT: Okay. Thank you. Anything else?

17 MR. WONG: Your Honor, can I make one point of
18 clarification?

19 THE COURT: Yes.

20 MR. WONG: It is just on the written description
21 issue. I wanted to make sure we're all clear. We are only --
22 the defendants are only asserting the written description as a
23 defense if you interpret the disputed preamble language of the
24 intended use as a limitation. To the extent you say that it
25 is not a limitation, as we have argued, then we won't have a

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1 written description defense. Just to be clear.

2 THE COURT: I understand.

3 MR. WONG: Thank you.

4 THE COURT: Okay. Great. Okay. I think we have
5 aired this. Anybody else over there suffering?

6 MR. D'AMORE: No. Thank you, your Honor.

7 THE COURT: Mr. Wong, you carried your side
8 completely. Thank you all for coming. I'm not going to rule
9 from the bench.

10 (Proceedings concluded at 3:40 p.m.)

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